MEDFUSION
2001/2010 with 2010i

1-800-358-6019

medfusion inc
A medex inc company
3450 River Green Court, Duluth, GA 30136, (USA) (404) 623-9809

"DEDICATED TO EXCELLENCE"

TABLE OF CONTENTS

SECTION PAGE

1. INTRODUCTION 1-2

2. SPECIFICATIONS 3-5

3. THEORY OF OPERATION 6-27

3.1 INTRODUCTION 6-8

3.1.1 Top Housing S/A 6
3.1.2 Slide Housing S/A 6-7
3.1.3 Bottom Housing S/A 7
3.1.4 Safety Features 7-8

3.2 MECHANICAL SYSTEM 8-12

3.2.1 Introduction 8
3.2.2 Top Housing Sub-Assembly 8
3.2.3 Bottom Housing Sub-Assembly 8
3.2.4 Slide Housing Sub-Assembly 9
3.2.4.1 Pumping Mechanism 9
3.2.4.1.1 Mechanical Resolution 10
3.2.4.1.2 Driving Mechanism 10
3.2.4.2 Syringe Retaining and Size Sensing 11
3.2.4.3 Position Sensing 11
3.2.4.4 Auxiliary Board and Cable Sealing 11-12
3.2.4.5 Provision for Cleaning 12

3.3 ELECTRICAL SYSTEM 12-20

3.3.1 Introduction 12
3.3.2 Main Board 12
3.3.2.1 Power Supply Circuit 12-14
3.3.2.2 Watchdog Circuit 14
3.3.2.3 Micro-Controller 14-15
3.3.2.4 LED Latches 15
3.3.2.5 Input Multiplexer 15-16
3.3.2.6 Analog-to-Digital (A/D) Converter 16
3.3.2.7 Alarm Circuit 16
3.3.2.8 Stepper Motor and Controls 17-18
3.3.2.9 LCD Display / Backlight 18
3.3.2.10 Interface Connectors 18

3.3.3 Auxiliary Board 18
3.3.3.1 Rotation Sensor 18-19
3.3.3.2 Size Sensor 19
3.3.3.3 Position Sensor 19
3.3.3.4 Force Sensor 19-20
3.3.3.5 Syringe Plunger Sensor 20
3.3.3.6 Controlled Voltage VA 20
3.3.4 Battery Pack 20

3.4 NOTES AND CAUTIONS FOR ASSEMBLING THE PUMP 21-25

3.4.1 Top Housing Sub-Assembly 21
3.4.2 Slide Housing Sub-Assembly 21
3.4.2.1 Assembling the Plunger Holder / Track S/A 22
3.4.2.2 Assembling the Slide Housing S/A 22
3.4.2.2.1 Assembling the Syringe Clamp, etc., to the S/A 22
3.4.2.2.2 Assembling the Plunger Holder/Track to the S/A ... 22
3.4.2.2.3 Assembling the Position Potentiometer to the S/A . 23
3.4.2.2.4 Assembling the Motor Mount to the S/A 23
3.4.2.2.5 Assembling the Leadscrew to the S/A 23
3.4.2.2.6 Assembling the Aux. Board to the S/A 23
3.4.2.2.7 Assembling the Worm and the Motor to the S/A 24
3.4.2.3 Adjustments and Calibrations 24
3.4.3 Bottom Housing Sub-Assembly 24
3.4.4 System Integration 24-25

3.5 ADDITIONAL DETAILED DISCUSSIONS 25-27

3.5.1 Motor Power Control 25-26
3.5.2 Occlusion Detection 26
3.5.3 Rotation Detection 26
3.5.4 Size Sensing 26
3.5.5 Position Sensing 27
3.5.6 Delivery Accuracy 27

4. MAINTENANCE 28-39

4.1 INTRODUCTION 28

4.2 PREVENTIVE MAINTENANCE 28

4.2.1 Performance Test 28
4.2.2 Cleaning and Miscellaneous 28-30

4.3 DISASSEMBLING THE PUMP 30-32

4.3.1 Disconnect Cables 30
4.3.2 Disassembling the Top Housing S/A 30
4.3.3 Disassembling the Bottom Housing S/A 31
4.3.4 Disassembling the Slide Housing S/A 31
4.3.4.1 Replacing Motor S/A or Worm 31
4.3.4.2 Position Sensor 31
4.3.4.3 Size Sensor 32
4.3.4.4 Auxiliary Board 32
4.3.4.5 Replacing Worm Gear and the Leadscrew 32
4.3.4.6 Disengaging the Track S/A from the Slide S/A 32
4.3.4.7 Disassembling Plunger Holder from Tack S/A 32

4.4 TESTS AND CALIBRATIONS 33-36

4.4.1 Tests 33
4.4.2 System Calibrations 33
4.4.2.1 Sensor Calibrations 33-35
4.4.2.2 QC Inspection 35-36

4.5 BATTERY CHARGING 36

4.6 OCCLUSION SENSING 36-37

4.7 TROUBLE-SHOOTING GUIDE 37

4.8 SERVICE AND LIMITED WARRANTY 38-39

APPENDIX

A. Assembly Drawings **40-61**

Final Assembly 41
Top Housing S/A 42
Bottom Housing S/A 43
Slide Housing S/A 44-45
Assemby Instructions for Slide Housing S/A *46-49*
Slide S/A 50
Plunger Holder / Track S/A 51
Slide Housing-2 S/A* 52
Assembly Instructions for Slide Housing-2 S/A *53-56*
Transducer S/A* 57
Assembly Instructions for Transducer S/A 58
Plunger Holder / Track II S/A* 59
Assembly Instructions for Plunger Holder/Track II S/A *60-61*

B. Schematic Diagrams **62-67**

System Block Diagram 63
Schematic, Main Board 64
Main Board S/A 65
Schematic, Auxiliary Board 66
Auxiliary Board S/A 67

C. Micro-Controller I/O Port Definitions **68**

D. System Performance Tests **69-75**

2000 Series Test Procedure 70-73
2000 Series Test Report 74-75

E. Spare Parts List and Test Fixtures **76-81**

F. Trouble-shooting Chart **82-83**

**These assembly drawings are for pumps which utilize the moving plunger retainer assembly.*

SECTION 1. INTRODUCTION

The purpose of this service manual is to provide information to biomedical personnel who are in the process of completing or have completed the Medex Service School for the Medfusion Models 2001, 2010 and 2010*i* *(hereinafter referred to as 2000 series)* syringe devices.

CAUTION:

THESE PUMPS SHOULD NOT BE SERVICED BY ANY PERSONNEL WHO HAVE NOT ATTENDED THE MEDFUSION 2000 SERIES SERVICE SCHOOL.

Attendees of the program receive a certificate upon completion of same. The manual is not a stand alone document for performing pump service and, as such, is intended to be an adjunct to the service school. The information presented in this manual has been verified. However, Medex assumes no responsibility for inaccuracies. Furthermore, Medex reserves the right to make changes to improve reliability, safety, function, or design. Check the date on this manual. If it is over two years, call Medex to determine if any changes have been made. Please refer to the current Operation Manual for detailed operating instructions.

This manual has been produced as technical support for your 2000 series infusion pumps. We would like to take this opportunity to remind you that another rich source of support is our Technical Support Department. It is our hope that our manual is as complete as possible, however there may be occasions when it will be difficult to "pigeon hole" a situation in this manual. Medex strongly encourages you to utilize this resource to avoid unnecessary repair returns and minimize costly down time.

In other words, please call our staff when you are troubled with a repair or if you are planning on sending it in. The Technical Support Department is available during regular business hours at 404/623-9809.

CAUTION:

Federal (USA) law restricts this device to the sale by or on the order of a physician.

Section 2:
Specifications

SECTION 2. SPECIFICATIONS (2001)

Overall Size	4.5" wide X 3.0" high X 7.5" long
Weight	2.5 Pounds
Accuracy	+/- 3%, excluding syringe variations
Infusion Modes	Continuous, Volume Over Time, Intermittent Auto, Intermittent Manual
Flow Rate	00.01 to 99.99 ml/hour in increments of 0.01, or 0.1 to 378.0 ml/hour in increments of 0.1
Syringe Selection	Three Manufacturers*: Becton-Dickinson (B-D) (B-D Glass); Monoject (Mono); Terumo (Terumo) Syringe Sizes: B-D 1, 3, 5, 10, 20, 30, 60 ml Mono 1, 3, 6, 12, 20, 35, 60 ml Teru 1, 3, 5, 10, 20, 30, 60 ml (Fill Volume: 1,3,6,12,25,35,60) B-D Glass 1, 3, 5, 10 ml Special request available for other syringe manufacturers.
Syringe Fill Volume	All syringe sizes will fill to maximum stated volumes.
Power	AC 95-135V, 60Hz; International voltages available. DC internal rechargeable batteries.
Syringe Programming	The pump automatically senses the syringe size when loaded properly.
Recharge Time	No longer than 16 Hours at 25 degrees C.
Battery Capacity	At 25 degrees C, a 16-hour charge will operate the pump for at least 10 hours at 5.0 ml/hour with a 60 ml syringe. **NOTE:** *Battery Capacity will vary with the depth of discharge during cycling.*
Alarms/Alerts	Near Empty, Empty, Volume Limit, Occlusion Low Battery, Depleted Battery, Battery In Use, Battery Charging System Malfunction Syringe Pops Out, Check Clutch, Battery Depleted/Plug In AC Invalid Size, Invalid Number Stop/Program, Deliver, Priming, Standby
Total Volume Delivered	000.00 to 999.99 ml, increments of 0.01 ml
Volume Limit	0.1 to maximum capacity of syringe size selected increments of 0.01 ml (slight variances may relate to software version in use).
KVO	0.1 to 9.9 ml/hour, increments of 0.1 ml/hour.

See Operations Manual for the software version of your pump.

**Trademarks of Becton-Dickinson, Sherwood Medical and Terumo respectively.*

SPECIFICATIONS (2010)

Overall Size	4.5" wide X 3.0" high X 7.5" long
Weight	2.5 Pounds
Accuracy	+/- 3%, excluding syringe variations
Infusion Modes	Body-weight (mcg/kg/min,mcg/kg/HR,MG/kg/min,MG/kg/HR), MG/HR, ML/HR, Volume/Time
Flow Rate	0.1 to 378 ml/hour dependent on syringe size selected.
Bolus Rate	Up to 378 ml/hour.
Syringe Selection	Three Manufacturers*: Becton-Dickinson (B-D) (B-D Glass); Monoject (Mono); Terumo (Terumo) Syringe Sizes: B-D 1, 3, 5, 10, 20, 30, 60 ml Mono 1, 3, 6, 12, 20, 35, 60 ml Teru 1, 3, 5, 10, 20, 30, 60 ml (Fill Volume: 1,3,6,12,25,35,60) B-D Glass 1, 3, 5, 10 ml Special request available for other syringe manufacturers.
Syringe Fill Volume	All syringe sizes will fill to maximum stated volumes.
Power	AC 95-135V, 60Hz; International voltages available. DC internal rechargeable batteries.
Syringe Programming	The pump automatically senses the syringe size when loaded.
Recharge Time	No longer than 16 Hours at 25 degrees C.
Battery Capacity	At 25 degrees C, a 16-hour charge will operate the pump for at least 10 hours at 5.0 ml/hour with a 60 ml syringe. **NOTE:** *Battery capacity will vary with the depth of discharge during cycling.*
Alarms/Alerts	Near Empty, Empty, Bolus Delivery, Occlusion Low Battery, Depleted Battery, Battery In Use, Battery Charging System Malfunction Syringe Pops Out, Check Clutch, Battery Depleted/Plug In AC Invalid Size, Invalid Number Stop/Program, Deliver, Priming, Standby
Total Volume Delivered	0000.0000 to 9999.9999 mg or ml.

See Operations Manual for the software version of your pump.

**Trademarks of Becton-Dickinson, Sherwood Medical and Terumo respectively.*

SPECIFICATIONS (2010*i*)

Overall Size	4.5" wide X 3.0" high X 7.5" long.
Weight	2.5 pounds
Accuracy	+/- 3%, excluding syringe variations.
Infusion Modes	**Body Weight Modes:** µg/kg/min, µg/kg/HR, MG/kg/min, MG/kg/HR **Mass Modes:** µg/min, µg/HR, MG/min, MG/HR, mU/min, mU/HR, U/min, U/HR **Continuous Modes:** ml/min, ml/HR **Volume Over Time Mode:** volume/time
Flow Rate	0.1-378.0 ml/HR dependent on syringe size selected.
Syringe Selection	Three Manufacturers*: Becton-Dickinson (B-D) (B-D Glass); Monoject (Mono); Terumo (Terumo) B-D 1, 3, 5, 10, 20, 30, 60 ml Mono 1, 3, 6, 12, 20, 35, 60 ml Teru 1, 3, 5, 10, 20, 30, 60 ml B-D Glass 1, 3, 5, 10 ml
Syringe Fill Volume	All syringe sizes will fill to maximum stated volumes.
Power	AC Adapter; DC Internal Rechargeable Batteries.
Syringe Programming	The pump automatically senses the syringe size when loaded.
Recharge Time	No longer than 16 hours at 25 degrees C.
Batttery Capacity	At 25 degrees C, a 16-hour charge will operate the pump for approximately 10 hours at 5.0 ml/hour with a 60 ml syringe. **NOTE:** *Battery capacity will vary with the depth of dis charge during cycling.*
Alarms/Alerts	Empty, Occlusion, System Malfunction, Low Battery, Depleted Battery, Check Clutch, Syringe Pops Out, Invalid Size, Invalid Number, Load Syringe Plunger, Alarm Audio Volume: Soft or Loud, Near Empty: Programmable between 5 and 60 minutes, Alarm Temporary Delay: 2 or 60 minutes, Stop/Program, Bolus Delivery, Deliver, End of Bolus, Battery Charging, Battery in Use, Priming, Standby Mode
Total Volume Delivered	0000.0000 to 9999.9999 mg, Units or ml.

See Operations Manual for the software version of your pump.

**Trademarks of Becton-Dickinson, Sherwood Medical and Terumo respectively.*

SECTION 3. THEORY OF OPERATION

3.1 ..... INTRODUCTION

The 2000 series syringe pump consists of three major subassemblies (S/A): Top Housing S/A, Slide Housing S/A, and Bottom Housing S/A. These three subassemblies simply snap together and are held in place with five (5) screws. They fit together using tongue and groove construction which makes the pump resistant to fluid entry. These housings are injection-molded with high impact resistant polycarbonate.

3.1.1 ..... Top Housing S/A

The Top Housing S/A consists of the Top Housing, Keypad, LCD display, and Main Electronic Board:

A membrane keypad with tactile keys is used to program the pump. The LCD display has 4 lines by 20 characters and a wide viewing angle. It is used to provide menu-driven programming, to display all programmed parameters and information, and to provide flexibility for future improvements. The LCD display is equipped with an LED backlight for low light viewing. The backlight is always on whenever AC power is used. When on battery power, the backlight is normally off. It can be turned on for approximately 15 seconds by pressing any key on the keypad.

Most of the electronics are contained on the Main Board attached to the top housing. The other small Auxiliary board is mounted on the slide housing. The brain of this pump is a single chip Micro-Controller with 32K bytes of nonvolatile memory. The memory spaces for the program and the data are dynamically partitioned without any change in the hardware. This feature provides for maximum flexibility, thus allowing future software upgrades. Also, bidirectional serial communication with other computer equipment is possible via the DIN connector.

3.1.2 ..... Slide Housing S/A

The Slide Housing S/A consists of the Slide housing, Mechanical pumping mechanism, Syringe barrel retainer, Sensors, and Auxiliary board:

The mechanical pumping mechanism consists of a stepper motor, a worm gearing system, a precision leadscrew, and a pair of fully engaged clutch nuts to propel the Track and the syringe plunger driver.

The syringe barrel retainer consists of a syringe barrel saddle and a syringe clamp. They are carefully designed so that virtually all types of syringes (1 cc to 60 cc) can be accommodated. The loading of the syringe is simplified by using the same procedure for all size syringes. The syringe barrel clamping system provides for syringe size sensing. By properly sensing syringe size one can prevent over/under-delivery caused by programming a syringe size different from the one actually being used. The barrel saddle position minimizes the overhang beyond the pump housing of the syringe plunger and the syringe barrel when a 60cc syringe is used.

The 2000 series syringe pump is equipped with an array of sensors for monitoring the rotation of the motor shaft, the movement of the syringe plunger driver, the force at the end of the syringe plunger, the size of the syringe, and the internal battery voltage. The outputs of the sensors are monitored by the Micro-Controller via Analog-to-Digital (A/D) converter to assure proper pump operation.

There is a new style plunger holder/track which affects the Model 2010*i*, Models 2001/2010 beginning with S/N 33601 and to all pumps that have had the plunger holder/track subassembly replaced with the new style track P/N 0-68-20A10-0-1. The most perceptible change to the track is that the retainer moves outward when the clutch is pinched. If you are uncertain as to whether you have the most current plunger holder/track, please call Technical Service at 1-404-623-9809.

The Model 2010*i* uses the Slide Housing-2 S/A, Plunger/Track-2 S/A which includes a syringe plunger detector. If the syringe plunger is not properly loaded during the syringe size confirmation or during the delivery, a message of "Load Syringe Plunger" and a continuous alarm will be given. For 2001/2010 pumps fitted with the new Plunger/Track 2 S/A, an "Occlusion" alarm will be triggered during the delivery in the same scenario in certain software versions (2001 - 1.4 or below: 2010-1.2 or below).

The back pressure inside the syringe develops a force (at the end of the syringe plunger) which is sensed by a strain gauge force sensor. The Micro-Controller uses the reading of this sensor and the size of the syringe detected by the size sensor to determine the allowable force at the end of the syringe plunger. An occlusion alert is signaled if the trip force for the specific syringe size is exceeded.

The Auxiliary board has an amplifier for amplifying the signal from the strain gauge, and an optical device to detect the rotation of the motor shaft. This board provides a convenient connection point for cables simplifying the integration of the subassemblies.

3.1.3..... Bottom Housing S/A

The Bottom Housing S/A consists of the Bottom housing, Battery pack, Audio Alarm, Power switch, and DIN connector.

Normally, the pump is powered by external AC power via the external plug-in AC adaptor. However, there is an internal battery pack to backup the operation of the pump in case of a power outage or during transportation. The battery is always being charged as long as the external AC power is applied.

The power switch is protected by a pair of switch guards to protect against being turned off accidentally. The DIN receptacle mates with the AC charger plug and has additional pins for future expansion (e.g., serial communication).

3.1.4..... Safety Features

Many safety features are carefully built into the pump. They are: the Watchdog circuit, Stepper motor control, Sensors, and System self-test.

The watchdog circuit monitors the proper operation of the Micro- Controller. The Micro-Controller must send at least a pulse to the watchdog circuit within a preset time interval, otherwise, the watchdog circuit activates the SYSTEM MALFUNCTION alert (LED & alarm) and disables the power to the stepper motor.

The stepper motor for driving the syringe plunger is directly controlled and driven by the Micro-Controller. The Micro-Controller must send out a proper sequence of waveforms to each of the four motor coils to turn the shaft of the motor. It is very unlikely that the motor can run away as long as the Micro-Controller is operating properly. If the Micro-Controller is not working properly, the watchdog circuit would activate an alert to stop the motor. If the motor driver fails, the motor will not run properly. When the rotation sensor detects this failure, an alert will be activated. If the motor is running, but the syringe plunger driver does not move (maybe due to defective clutch nuts or an improper engagement), the position sensor will detect this problem. If the syringe plunger is manually moved during delivery, the position sensor will detect this problem and sound an alarm.

The accuracy of the pump delivery rate depends mainly on the accuracy of the leadscrew and the system clock. There is no need for any adjustment or calibration for the delivery rate as long as the program inside the Micro-Controller is accurate. The integrity of the program is verified by performing a check sum test on the program after the pump is turned on.

3.2 ..... MECHANICAL SYSTEM

3.2.1 ..... Introduction

The 2000 series syringe pump consists of three major subassemblies: Top Housing S/A, Bottom Housing S/A, and Slide Housing S/A. These subassemblies are supported by 8 major injection molded plastic parts: Top Housing, Bottom Housing, Slide Top, Slide Bottom, Syringe Saddle, Syringe Clamp, Track, and Syringe Plunger Holder (or Driver). The Slide Housing S/A, the most complex assembly, hosts the entire pumping mechanism and all the pump sensors.

3.2.2 ..... Top Housing S/A (P/N 1-68-20A00-0-X, Appendix A)

The Top Housing S/A holds the Keypad, the LCD display, and the Main board. The groove around the Top housing matches the tongue of the Bottom housing and Slide housing. This tongue and groove construction improves the resistance to fluid entry.

3.2.3 ..... Bottom Housing S/A (P/N 1-68-20A01-0-X, Appendix A)

The bottom housing holds the battery pack, the alarm, the power switch, and the DIN connector. The battery pack is secured to the bottom housing by a strip of double-side tape. The tape has a very aggressive adhesive which can only be removed with a knife. The Power switch together with a pair of switch guards snaps into the bottom housing. The DIN connector is secured to the bottom housing with a ring nut. The bottom housing also has a sliding guide and acts as a mechanical stop for the syringe clamp. There are two threaded inserts on the outside surface of the bottom housing for mounting the pole clamp. There is a recess on one exterior surface for placing the brief instruction label.

3.2.4..... Slide Housing S/A (P/N 1-68-20A02-0-X, Appendix A)
Slide Housing-2 S/A (P/N 1-68-20A07-0-X, Appendix A)

The Slide Housing S/A is made up by the Slide S/A, the Track/Plunger Holder S/A, the pumping mechanism, and various sensors.

The Slide S/A is assembled by bonding the Slide Top housing and the Slide Bottom housing. The syringe saddle is snapped in place and retained with two roll pins. After bonding, a worm bushing is inserted using a special tool. The Slide S/A cannot be disassembled after bonding. The Track / Plunger holder S/A consists of the Track, the Plunger holder, the Force sensor, and the Mounting hardware. Metal inserts are molded into both the Track and the Plunger holder to provide a solid support for the force sensor. The force sensor is made of a strain gauge reed and a blank reed. Two reeds are used to reduce the variation of the gauge output when the force is not applied at the center point of the strain gauge. Special surface treatment and tight dimensional tolerances for the mounting hardware are specified to improve the linearity and the stability of the final force sensor assembly.

The Plunger/Track-2 S/A uses a different method to mount the force transducer. It consists of Track-2, Plunger Holder-2, Plunger Retainer-2, Force Transducer Cable S/A, Switch Cam, Transducer Spacers and mounting hardware. Four Transducer Spacers replace the two metal inserts inside the old track and plunger holder. A Dome Switch is included in the new Force Transducer Cable S/A to be actuated by a Switch Cam which is linked to the moving Plunger Retainer-2. The Plunger Retainer is a moving part. If the syringe plunger is not held properly by the retainer, the Dome Switch is actuated via the Switch Cam, and an unusual high force reading is detected.

Building this subassembly is not an easy task, therefore, caution and care should be taken and the proper tools must be used. Otherwise, the strain gauge can be easily damaged, or the performance of the force sensor will be adversely affected.

- Note the orientation of the nut plate holes during assembly.
- The reeds must be mounted perpendicular to the top surface of the plunger holder. A clamp should be used to assist the assembly.
- Shims should be used when assembling the plunger holder to the track to control the gaps between them. The gaps should be symmetrical on either side of the plunger holder. The front side gap should be the same thickness as the shim.
- The proper amount of torque must be applied to the socket head screws to assure the stability of the force sensor.
- There should be no mechanical interference between the plunger and the track.

3.2.4.1 ..... Pumping Mechanism

The mechanical pumping mechanism is the heart of the syringe pump. This mechanism uses a stepper motor coupled to a worm gearing system to turn a precision leadscrew. The turning of the leadscrew propels the Track (via a pair of fully engaged clutch nuts) and advances

the plunger driver (mounted on the Track) which pushes the syringe plunger thus expelling the fluid inside the syringe barrel.

3.2.4.1.1 ... Mechanical Resolution

The stepper motor's step angle is 7.5 degrees. The worm gearing ratio is 1:44. The leadscrew has a pitch length of 20 threads per inch. Thus each step of the motor advances the syringe plunger 0.00002368 inches.

3.2.4.1.2 ... Driving Mechanism

The stepper motor is mounted on a bracket on the slide housing. The bracket must be aligned with the worm bushing hole by using a special alignment tool. As long as this bracket is not removed, there is no need for realignment. The motor shaft couples to the worm via a shaft driver on the motor shaft and a shaft coupler on the worm. The black/white markings on the shaft coupler are used to detect motor shaft rotation. A small amount of grease (Dow Corning 111 Valve Lubricant & Sealant) is placed inside the shaft coupler to dampen the hammering noise generated by the shaft driver at low speeds. The worm tip is supported by a worm bushing inserted inside the slide housing.

The worm is coupled to the leadscrew via a 44-tooth worm gear. One end of the leadscrew is supported by a bushing and the other end is supported by a bearing. E-clips are used to retain the leadscrew in position. The following cautions should be taken to minimize any friction which may reduce the pump output torque:

- Follow the procedure carefully to provide for an adequate gap between the leadscrew and the thrust bushing on the motor side. This gap is necessary to assure that there is no unwanted load on the leadscrew. The leadscrew should turn freely when there is no load (e.g., the clutch is opened).
- Be careful not to damage the teeth of the worm gear or the surface of either the leadscrew threads and the worm threads during assembly or disassembly.

A pair of spring-loaded half clutch nuts engage the leadscrew to the track. The pair of half clutch nuts form a 360 degree engagement onto the leadscrew and transform the rotation of leadscrew to a linear movement of the track. There is a clutch key next to the clutch nuts to secure the engagement of the clutch nuts to the track. A clutch actuator rod links a clutch lever to the clutch nuts and is secured by a clutch rod cover and two screws. Thus, by pinching the clutch lever, the clutch nuts open and the track is disengaged from the leadscrew. The track can be manually moved in and out.

A syringe plunger driver is mounted on the track. The movement of the track causes the syringe plunger driver to push the plunger of the syringe to expel the fluid inside the syringe.

There is a molded gear rack inside the track which engages a potentiometer via a cluster gear train. The linear movement of the track rotates the potentiometer shaft so that the track movement can be monitored.

3.2.4.2.....Syringe Retaining, Size Sensing, and Syringe Plunger Detection

The syringe plunger detection mechanism consists of a dome switch (built into the force transducer cable S/A), a switch cam with an adjustable setscrew, and the plunger retainer. The dome switch, when activated, will signal improper syringe plunger loading. The setscrew should be adjusted so that the actuation point for the dome switch is when the gap between the plunger retainer and the holder is between 0.025" and 0.015". The dome switch has 0.010" post traveling distance after actuation. Thus, the gap between the plunger retainer and the holder must be greater than 0.035" to allow the force transducer to be in normal operating condition.

The syringe barrel retaining system consists of a syringe barrel saddle and a syringe clamp. The syringe saddle is assembled to the slide subassembly and secured by 2 pins that are potted in the slide subassembly. The syringe clamp is a clear plastic clamp with a gear rack. It is inserted into a chimney-like slot on the Slide top and the gear rack is engaged with a spur gear located on the shaft of the size sensing potentiometer. A rubber boot is installed around the syringe clamp to discourage fluid entry.

The engagement (timing) between the syringe clamp gear rack and the size gear must be carefully adjusted so that the center tab of the potentiometer always stays within the electrical range of the potentiometer for the lowest and highest useful positions of the clamp. The potentiometer spur gear is spring loaded with a torsion spring so that the syringe barrel is automatically held down in place when the clamp is released. The pre-loading amount should be carefully controlled. The clamp does not spring down easily if there is not enough pre-loading of the spring. However, permanent damage might happen to the spring if there is too much pre-loading. After the adjustment of the timing and pre-loading, the potentiometer and the spring must be secured tightly with the clamps and screws for mechanical stability.

3.2.4.3.....Position Sensing

A gear rack is molded into the inside wall of the track. This gear rack engages with the position gear at the shaft of a position sensing potentiometer via a cluster gear inserted in the Slide Housing. The potentiometer is secured to a potentiometer holder with a nut. The holder is then secured to the slide housing with two screws. The engagement (timing) of the position gear with the cluster gear should be carefully adjusted so that the center tab of the potentiometer always stays within the electrical range of the potentiometer when the track is moved to the most inward or extended positions. The slot at the potentiometer holder is used to adjust the tightness of the engagement to obtain a smooth track movement with minimal backlash. The two screws must be tightly secured after the adjustment for mechanical stability.

3.2.4.4.....Auxiliary Board and Force Cable Sealing

The force sensor flex cable is brought into the underside of the slide housing through an opening of the slide. This opening is sealed off with a pair of rubber cable seal plugs. The slide housing

cable length should be carefully controlled since it affects the rolling action of the cable inside the track. The cable and the solder joints at the end of the cable should be carefully handled and secured to the slide housing with double-sided tape.

The Auxiliary board provides a convenient place for terminating sensor connectors and simplifies the cabling of the final assembly. The board is mounted to the slide housing by two screws. There is an opto-sensor on the board which detects motor shaft rotation. The force sensor signal is conditioned at the Auxiliary board before being converted by the A/D converter on the Main board.

3.2.4.5 ..... Provision for Cleaning

In other typically designed syringe pumps, a slot and a pair of rubber wipers are used to link the leadscrew to the plunger driver. This type of design has some disadvantages. A small object can easily fall into the slot and get trapped between the leadscrew and the clutch nut. The movement of the plunger might be blocked by this trapped object. Also, fluid can easily enter the slot and contaminate the leadscrew or possibly the electronic circuitry inside the pump. Cleaning a major spill is difficult.

The linkage of our pump between the track and the leadscrew is designed so that the leadscrew is almost inaccessible to the user. This design reduces the possibility for blockage of the track movement by a trapped object. The design of the leadscrew compartment also provides a better way for cleaning fluid spill and fluid entry into the pump. A door is provided for covering the leadscrew compartment. This door can be removed to clean the leadscrew compartment if there is a major spill.

3.3 ..... ELECTRICAL SYSTEM

3.3.1 ..... Introduction

The pump's electrical system resides on the Main board and the Auxiliary board. Most of the circuit is on the Main board. Refer to the system block diagram in Appendix B.1.

3.3.2 ..... Main Board

The Main board consists of the following circuits: Power supply circuit, Watch-dog circuit, Micro-Controller, LED circuit, Input interface, Analog-to-Digital converter, Alarm circuit, Stepper motor driver, LCD & Backlight circuit, and the connectors for Keypad, LCD, Motor, Alarm, AC charger and the serial communication.

3.3.2.1 ..... Power Supply Circuit

The requirements for the power supply circuit are: to convert the AC power input to a DC power so the pump can be operated regardless of the condition of the battery, to charge the battery regardless of the position of the power switch, and to switch the battery power whenever AC power input is interrupted. The power supply consists mainly of a rectifier, power switch, regulators, and the battery charging circuit.

- AC to DC conversion:

The AC power from the AC charger is fed to the Main board via the DIN connector. The AC voltage is converted to a rectified DC voltage (Vx) via a full-wave bridge rectifier CR1 and a 3300UF capacitor C32. A slo-blo fuse is inserted between the AC input and the rectifier for the over-current protection. The rectified DC voltage (Vx) (through the power switch J4B-1,2) provides the power for the LCD display backlight, and serves as the main power for the pre-regulated Voltage (Vm) via the regulator U8 (8.3V) and the diode D15. The voltage at Vx also feeds the power to the battery charging circuit.

- Battery charging circuit:

The Battery charging circuit will constantly charge the battery at a rate of 1/10C (i.e., 110mA) when the battery power is low or depleted. The charging circuit consists of regulator U11 and resistors R37, R38, etc. Regulator U11 and resistor R37 (11.5 ohm) form a 104mA constant current source (i.e., 1.2V/11.5) for charging the battery. Diode D16 prevents the battery from feeding the battery power back to the charging circuit if the AC power is absent. Diode D16 and resistor R37 also provide a sensing voltage for the transistor Q9 to indicate that charging current is flowing to the battery. If there is none or little current flowing through R37 and D16, the voltage between the base and the emitter of Q9 is so small that Q9 does not conduct. Hence, the green Charging LED would not light.

- Battery Detection:

There is a resistor R17 (750K ohm) connecting between pin 1 and 4 of the battery connector J4A. Both pin 1 and pin 4 of the battery pack connector are connected together to the positive terminal of the battery pack. If the battery pack connector is properly plugged into the connector J4A on the Main board, then R17 is shorted, and the normal charging current can be applied to the battery. If the connector of the battery pack is not properly plugged in, the pump can still be operated on AC power. However, the voltage drop at R17 helps the Micro-Controller detect the absence of the battery pack and to signal the low / depleted battery condition (LED & alarm).

- Power switch circuit:

Because the battery should always be charged regardless of the power switch position, the battery is always connected to the charging circuit. The charging circuit and the battery are directly connected to the AC input and will not be interrupted by the power switch. The power switch is a double-pole single-throw switch for providing two separate power pathways for the pre-regulated voltage (Vm) to operate the pump: one for the battery power and the other for the rectified power (Vx) from the AC input. Diodes D15 and D14 are used to isolate these two paths. The battery voltage can be monitored by the Micro-Controller via the Analog-To-Digital (A/D) converter (U6) and the voltage divider (R3,R4). The presence of AC power can be monitored by the Micro-Controller by detecting the voltage at Vx via the input multiplexer U4 and R11, D6, D7, R13.

- Various DC Voltages (Vm, +5V, Vc, VA):

The regulator U8 (together with resistors R19,R18) regulates the rectified voltage Vx to 8.3V, and serves as the main source of the power for the pre-regulated voltage Vm via the diode D15. The voltage at Vm will be switched automatically to the battery voltage as soon as the output voltage at U8 is less than the battery voltage. This condition occurs when the AC power is interrupted, or the battery voltage has been overcharged (higher than 8.3V).
The rectified voltage Vx supplies the power to the LCD backlight via a power resistor R16. The backlight current is about 130mA when powered by Vx. The voltage drop at R16 is about 7.5V. The power resistor withstands heat better than a semiconductor. If there is no AC power, the backlight will not be lit unless the Micro-Controller turns on Q3 to supply current to the backlight from the regulated voltage +5V.

The pre-regulated voltage Vm provides the power to the rest of the circuits, i.e., the stepper motor, the alarm, and the regulated voltage +5V. The regulated voltage +5V is derived from Vm with a low dropout voltage regulator U1. The majority of the IC's are powered by the +5V directly, i.e., LED latches (U2), Watch-dog circuit (U3), and the input multiplexer (U4). However, a de-coupling filter (R35,C30,C31) is inserted between +5V and the Micro-Controller. Another de-coupling filter (R9,C1,C2) is inserted between +5V and the LCD display (DP1). A switching transistor (Q4) provides a controlled voltage (VA) for the power to the Analog-To-Digital (A/D) converter and the sensors on the Auxiliary board via connector J5 (a 14 pin ribbon cable).

3.3.2.2 ..... Watchdog Circuit

An independent watchdog circuit is implemented to confirm that the Micro-Controller hardware is operating properly (i.e., not crashed). It is not the function of the watchdog to validate the software (i.e., to identify software bugs). If the Micro-Controller is crashed (i.e., not properly executing the software program), the watchdog signals alert and turns off the power to the motor.

The watchdog circuit is a simple R-C timing circuit consisting of R14,C10 and other supporting circuit (U3B, C9, R15, D8, Q6, U3A, Q5, LD7, D23, D3). Capacitor C9 blocks the DC signal allowing only the AC pulses to pass through. If the Micro-Controller fails to send a pulse to the watchdog circuit (via port pin P3.0) within a preset time interval (determined by R14 and C10), the voltage at C10 will be charged up and exceed the threshold voltage of the Schmitt-inverter U3A. The output at U3A becomes low thus turning on the SYS. MAL. LED (LD7) via transistor Q5. It also turns on the alarm via U3E, and disables the power to the motor via the diode D23 and an inverter at pin 1 of U10. This SYS. MAL. signal can be monitored from the outside of the pump via pin 7 of the DIN connector.

3.3.2.3 ..... Micro-Controller

The brain of the pump is a Micro-Controller (DS5000-32 by Dallas Semiconductor). This 40-pin Micro-Controller (U5) consists of: a microprocessor (similar to Intel 8051), 32K-byte Nonvolatile RAM (battery backup) which can be dynamically configured to different sizes for the Program ROM and/or the Data RAM, 32 parallel I/O ports, two 16-bit timers, and

serial I/O ports. The usages and the definitions for these parallel I/O ports are described below and are also summarized in Appendix C.

Port 0 lines are pulled-up by 10K-ohm resistors. P0.0-P0.3 output the stepper motor waveform to the Driver (U10) to run the motor. P0.4 turns on /off the alarm. P0.5 and P0.6 are not used. P0.7 controls the power (VA) to the A/D converter and the sensors on the Auxiliary board via Q4.

Some lines of Port 1 have multiple usage. P1.0-P1.3 are used as input lines for the keypad scanning and for other input signals via the input multiplexer. P1.3 is also used to output a signal to the A/D converter. P1.4 controls the power for the stepper motor via an inverter (U10 pin 1) and an MOSFET transistor (U7). P1.5 and P1.6 output the control signals to the LCD display. P1.6 also controls the input multiplexer (U4). P1.7 outputs the clock signal for the LED latch/ driver (U2).

Port 2 (P2) is used mainly as a slow data/control bus which supplies 8-bit data to the LCD display and the LED latch/driver (U2). P2.0-P2.3 output scanning signals for the keyboard. P2.4 and P2.5 are used to interact with the A/D converter (U6). P2.7 also controls the input multiplexer (U4).

Port 3 is used for miscellaneous controls. P3.0 outputs pulses to the watchdog circuit. P3.1 and P3.2 are reserved for the serial communication via the DIN connector. R20,R21,D26-D29 are used for the protection of the port lines against excessive voltage from the outside. P3.3 controls the READ/WRITE operation of the LCD display. P3.4 controls the Volume Limit LED. P3.5 turns ON/OFF the backlight when AC power is not present. P3.6 controls the loudness of the alarm. P3.7 outputs the Chip-Select signal for the A/D converter.

NOTE: *For 2010i or 2000 series pumps with RS232 software, P3.2 and P3.0 functions are reversed.*

3.3.2.4 ..... LED Latches /Flasher

There are different LEDs to provide the visual signals for different kinds of alert conditions. The Micro-Controller stores the current status of the LEDs into an 8-bit latch (U2) via P2 port and P1.7 line. The Volume Limit LED (LD5) is directly controlled via P3.4. The SYS. MAL LED (LD7) is directly controlled by the watchdog circuit. The Battery Charging LED (LD11) is controlled by the charging circuit. The blinking for some LEDs (Stop/Program, Deliver, and Battery-in-use) is implemented via a slow oscillator (U3B, R12, C11, D5, R10, Q7). D5 and R10 are added to the oscillator to reduce the "ON" blinking interval conserving the battery energy.

3.3.2.5 ..... Input Multiplexer

Some input signals and sensors are detected by the Micro-Controller via a digital multiplexer (U4). Any of two banks of 4-input lines can be selected via Port P2.7. The output lines of the multiplexer (pin 4,7,9,12) are read by the Micro-Controller via P1.0 through P1.3, if P1.6 is set to 0 (chip-enable for U4). When P2.7 is set to 1, the keypad column condition can

be read. When P2.7 is set to 0, the motor shaft rotation sensor (pin 2), the presence of AC power (pin 5), and two other input signals (pin 11, 14) can be detected. The rotation sensor signal (from the Auxiliary board) is shaped by a schmitt inverter (U3C). The presence of AC power is detected via R11,R13, D6,D7 and pin 5 of RN1. If AC power is present, the rectified voltage Vx varies from 9V to 16V, the voltage at the junction of D6,D7,R13 is greater than 4.5V, the voltage at pin 5 of U4 is between 4.5V and 5V. If there is no AC input, pin 5 of U4 is about 0.6V. Thus the condition of the AC power can be detected by the Micro-Controller.

The keypad is configured as a matrix of 4 columns and 4 rows. The Micro-Controller sets up a 0V to only one of the rows sequentially via P2.0-P2.3 & D9-D12, and reads the condition of the corresponding column via pins 3,6,10,13 of U4 and P1.0-P1.3. If none of the keys of the scanned column is pressed, a logical '1' (5V) is sensed at each column line. On the other hand, a logical '0' (0.6V) is sensed for each depressed key of the scanned column. By scanning the column sequentially, the Micro-Controller can interpret the status of the keypad. Diodes D9-D12 are used to isolate the interference among P2.0-P2.3 lines when keys from different columns are depressed at the same time. Diodes D30-D45 are used to protect the port lines and U4 against any excessive static voltage.

3.3.2.6 ..... Analog-to-Digital (A/D) Converter

The converter U6 is a 4-channel Analog-to-Digital (A/D) Converter which converts the analog voltage of the selected channel to a digital reading. This reading can be retrieved by a series of pulses from the Micro-Controller (via pins 2,10,12,13 of U6). The digital section of the IC is powered by +5V. However, the reference voltage for the A/D (at pin 9) is powered by voltage VA which can be turned off by P0.7 via Q4 to conserve battery power. The assignments for the analog channels are:

Channel 1 (U6-3) : Force sensor
Channel 2 (U6-4) : Size sensor
Channel 3 (U6-5) : Position sensor
Channel 4 (U6-6) : Battery voltage

3.3.2.7 ..... Alarm Circuit

The alarm circuit consists of an alarm (via connector J1), a switching transistor (Q1), the loudness control (Q2, R8), and some gating components (D3, D4, R7). The alarm supply voltage is the pre-regulated voltage Vm. The alarm is switched on/off by the control voltage at the gate of Q1. This control voltage is high if the Micro-Controller wants to turn on the alarm by setting P0.4 high, or if SYS. MAL. condition signal is low (i.e., System Malfunction occurs). The alarm can only be turned off if there is no SYS. MAL. signal. The loudness of the alarm is controlled by P3.6 via Q2 and R8. If P3.6 is high, Q2 is shorted and the alarm volume is loud. If P3.6 is low, then Q2 is turned off. Resistor R8 is in series with the alarm to make the alarm volume soft.

3.3.2.8 ..... Stepper Motor and Controls

A 7.5 degree 4-phase unipolar stepper motor is used in the pump. Basically, the motor consists of a rotor with permanent magnetic poles, and a stator with 4 coils. The coils must be energized in a very specific sequence for the rotor to rotate properly. The waveforms needed to drive the coils of the motor are provided directly by the port lines of the Micro-Controller, i.e., P0.0-P0.3. U10 is a open-collector Darlington Driver and is used to convert the controlling waveform into the switching sequence to energize the motor coils. Pins 2-5 of the pull-up resistor pack RN2 provide the bias current for the Darlington drivers. Diodes D18-D22 are to protect port lines of the Micro-Controller from going negative due to the spike from the switching motor coils.

The motor supply voltage is the pre-regulated voltage Vm and is controlled by P1.4 (via U10 pin 1, U7 and R24) and the SYS. MAL. signal (via D23). A high current is supplied to the motor coils through U7 if U7 is turned on by P1.4. U7 can be turned off (if P1.4 is set to 0) to significantly reduce the motor current because of the insertion of R24.

The motor current control is very important for reducing the energy consumed by the motor to conserve the battery energy when running at low speeds, and to reduce the heat produced by the motor. The current reduction is made possible with the use of an unidirectional transmission system and a stepper motor. The pump's unidirectional transmission system consists of a leadscrew, a worm, and a worm gear. This system only allows the motor to deliver torque to drive the syringe, and prevents the reactional load (caused by driving the syringe) from generating enough torque to overcome the motor's holding torque thus preventing reverse rotation of the motor. Because of this unidirectional feature, when the motor is running at low speed, high current is only needed to advance the rotor to the next position. As soon as the rotor reaches and stops at the desired position (approximate 10ms), the current can be cut back to a lower level. This low current provides additional holding torque to the motor's residual holding torque and holds the rotor in the new position for the duration of the current step. Thus, the energy requirement for the motor during low speed operation can be significantly reduced. If a current meter is used to monitor the motor current, it can be observed that the current for the motor increases as the delivery rate increases. It reaches a maximum current within a speed range (B-D 60cc syringe, 80ml/hr through 200ml/hr, i.e., the motor pulse interval is less than 10ms). Beyond this range, the current decreases as the delivery rate increases. This decrease is realized because the motor is an inductive device and there is always a resistance to the current change in the motor coils. The current supplying the motor coils can not reach the maximum value (saturation) when they are switched on/off at high speed.

A low SYS. MAL. signal overrides ,via diode D23, the control to the motor current by the P1.4 line and reduces the motor power to a low current mode. The motor does not have enough power to advance the rotor to the next position in the low current mode. Thus, the motor shaft would not turn as long as the SYS. MAL. signal remains low. It is very difficult for the motor to "runaway" due to a hardware failure. The reasons are:

- In order to turn the rotor of the motor, four sets of specific waveforms for four motor coils are required. These waveforms can not be generated if the Micro-Controller crashes.

- The watchdog will trigger a low SYS. MAL. signal to prevent the motor from running after the Micro-Controller crashes.

- The motor would not run properly if the motor driver U10 fails because the motor coil switching sequences would not be correct. The Micro-Controller will sense this problem by using the rotation detector and signal an alert.

3.3.2.9 ..... LCD Display / Backlight

The LCD display requires an 8-bit data line (D0-D7), and 3 control signals (E,RS,and R/W). The data lines are supplied by P2.0-P2.7. The E (Enable) line is P1.5. R/W (Read/Write) line is P3.3 which is always low to write to the LCD. RS (Register Select) line is P1.6 which also controls the input multiplexer. The LCD display can be backlit by turning on the LED backlight (BL pins). The backlight is always turned ON when the AC power is present, and can be "on demand" turned ON for a short period of time when battery power is used. This requirement is accomplished by connecting the rectified voltage Vx to the LCD backlight via a current limiting power resistor R16. The Micro-Controller can turn on the backlight by supplying +5V through the transistor Q3 with a control signal form P3.5. R1 provides additional current limiting to the backlight. Diodes D1 and D2 are used to isolate the two different power sources to the backlight.

3.3.2.10 ..... Interface Connectors

The Main board provides connectors for interfacing the different hardware components, i.e., Alarm(J1), Motor(J7), LCD display(J2), Auxiliary board(J5), Keypad(J3), battery & power switch (J4), AC charger and serial communication (J6). Both J4 and J6 are 8-pin connectors but J6 has a key at pin 2. J6 consists of a 3-pin connector (for the charger) and a 5-pin connector (for serial communication etc.). J8 consists of two 4-pin connectors for the power switch and the battery. Make sure that the polarity and orientation of the connectors are correctly installed after the pump is serviced. Otherwise, the Main board could be damaged. Also, the cables must be properly routed to prevent them from being pinched between the Main board, the Auxiliary board, the battery, the motor, the power switch, and the DIN connector.

3.3.3 ..... Auxiliary Board

An Auxiliary board is mounted on the Slide housing S/A to provide a base for connecting the different sensors inside the pump, i.e., the force sensor form the plunger driver, the size potentiometer from the syringe clamp, the position potentiometer from the Track, and the motor shaft rotation sensor.

3.3.3.1 ..... Rotation Sensor

The rotation sensor is a reflective opto-sensor OP1 consisting of a photodiode and a photo-transistor mounted on the Auxiliary board. The photodiodes emits light to the motor shaft coupler. The reflected light is sensed by a photo-transistor inside OP1. The shaft coupler has 4 sides. Two opposite sides are painted black. Thus, there are 4 transitions for each motor shaft

rotation. The quality of the signal at the collector of the photo-transistor depends on the focal distance of the OP1 and the light intensity of the photodiode. The seating height of the opto-sensor OP1 to the Auxiliary board is pre-calibrated for the best focused condition between OP1 and the shaft coupler. A single-turn trim pot VR1 is used for adjusting the light intensity emitted by the photodiodes.

3.3.3.2 ..... Size Sensor

The size sensor is a single-turn potentiometer VR3 engaged to the syringe clamp via a rack and pinion arrangement. When the syringe clamp is lifted, the potentiometer shaft turns. Thus, for each syringe size, there is a corresponding angular position of the potentiometer shaft, and the syringe size is converted to the voltage at the potentiometer center tab. The engagement (timing) between the pinion on the potentiometer shaft and the molded gear rack on the syringe clamp must be properly adjusted so that, for all syringe sizes, the potentiometer center tab always stays within the electrical range of the potentiometer. Capacitor C104 minimizes any high frequency transient noise picked up by the potentiometer. Due to linearity variations of the potentiometer, a calibration process uses the sizes of known syringes to establish a formula to convert the resistance value for unknown syringe sizes resulting in size recognition for these syringes.

3.3.3.3 ..... Position Sensor

The track's linear displacement is converted to a voltage via the position potentiometer. The spur gear on the potentiometer shaft engages with a cluster gear and then to a molded gear rack inside the track. The engagement (timing) between the spur gear and the gear rack must be properly adjusted so that the potentiometer center tab remains within the electrical range of the potentiometer when the track is at its maximum extended position or at the most inward position. Capacitor C103 minimizes any high frequency transient noise picked up by the potentiometer. Due to linearity variations of the potentiometer, a calibration process uses the most extended position and the most inward position to establish a formula to convert a resistance value to a position reading to check the track movement. This method is also used to monitor the remaining fluid volume inside the syringe. An alert signal will be given if the Micro-Controller detects no track movement.

3.3.3.4 ..... Force Sensor

A strain gauge sensor is attached to the plunger driver mounted on the track to sense the force required to push the plunger of a syringe during delivery. The signal generated at the gauge is transmitted to the Auxiliary board via a flat cable, and is conditioned by the amplifier circuit on the Auxiliary board. The amplifier consists of U101 and the associated resistors. The capacitors C101,C102, and C105 are used for limiting the bandwidth of the amplifier and reducing the high frequency transient noise. U101A is an inverted amplifier with an approximate gain of 14. R107 and R108 provide the bias voltage for the amplifier. The voltage difference between the gauge's center tab and the bias voltage, as well as the voltage changes generated by the applying force are amplified by U101A. It is very important to make sure that R107 and R108 are closely matched to prevent the difference in bias voltages from saturating the amplifier. The amplified signal at pin 1 of U101A is amplified again by another inverter U101B with a gain of 39. R109, R110 and VR2 are used to adjust the combined offset voltage

from U101A and U101B. The adjustment brings the voltage at pin 7 of U101B to a lower voltage so that the amplifier U101B will not be saturated by the gauge signal when a very high force is applied to the gauge.

3.3.3.5 ..... Syringe Plunger Sensor

The electrical circuit for the syringe plunger sensor is the dome switch (built into the force transducer cable S/A) and the force transducer. When the dome switch is activated, it will cause a short-circuit to one-half of the force transducer bridge and cause an unusual high sensor reading. This condition can be used to indicate the improper syringe plunger loading condition. The force sensor will function normally as the occlusion sensor if the dome switch is open.

3.3.3.6 ..... Controlled Voltage VA

The supply voltage for all the sensors and the amplifiers is voltage VA (a gated +5V), the same voltage for the reference voltage of the A/D converter. VA is turned off to conserve energy when the sensors are not active. The digital ground (pin 12 at J103) for the rotation sensor is separated from the analog ground (pin 14 at J103) for other sensors. They are joined together at the A/D converter. The unused connector at J104 is for future expansion.

3.3.4 ..... Battery Pack

The battery pack consists of 6 rechargeable Ni-Cad battery cells in series. Each battery cell is a SC size cell with 1.2AH capacity. A 4-pin connector is used to link the battery pack to the Main board. The negative terminal of the battery (black wire) is connected to pin 3. Two red wires are attached to the positive terminal of the battery pack. They are connected to pins 1 and 4. Upon plugging the connector into the Main board, the two red wires short-circuit the resistor R17 on the Main board to let the Micro-Controller know that the battery pack is properly connected. The battery is designed as a backup power supply when AC power is interrupted. The pack is always in the charging mode as long as AC power is applied regardless of the power switch position. When the battery is not fully charged, the charging current is about 104MA.

Some specifications from the battery manufacturer deserve attention:

- The majority of the battery energy lies between 7.6V and 7.3V.
- The battery can supply more than 500 charge/discharge cycles (conservative number, 2000 cycles according to the chart) when used repeatedly.
- The shelf life of the battery: The capacity retention of the battery depends on the storage temperature. It will retain 50% capacity after 6 months of storage at 20 degree C. The charging acceptance of the battery is temporarily decreased after long-term storage, but returns to normal condition after 1-3 charge/discharge cycles.
- The battery cell is sealed and leakproof thus providing safety and maintenance-free service.

3.4 ..... NOTES AND CAUTIONS FOR ASSEMBLING THE PUMP

3.4.1 ..... Top Housing S/A (P/N 1-68-20A00-0-X) (Appendix A)

In order to assemble the Main board to the top housing, the keypad connector from the top housing must be plugged into the right-angle 9-pin connector of the Main board. Then the connector for the LCD display is engaged and the Main board is mounted onto the top housing, assuming that the LEDs on the Main board are properly aligned into the holes on the top housing. Three long spacers (brass & nylon) and three screws secure the Main board to the top housing.

The following inspections should be performed after assembling:

- The keypad connector should be "fully" engaged with the pin. (i.e., minimum exposure of the pin can be observed). The connector and pins can be inadvertently slightly disengaged when trying to engage the LCD connector to the pins on the Main board. If the keypad connector is not fully engaged, the pump could have intermittent keypad problems, or if totally disengaged due to mechanical shock the keypad would not function.

- Each of the three long spacers is made of a short brass spacer and a nylon spacer bonded with thread lock adhesive. The two parts should be tightly engaged and bonded because the combined length of the spacer affects the final assembly of the three major assemblies (i.e., Top, Slide, and Bottom). Also, the three spacers must be tightly threaded, with a tool, into the top housing screw studs. The threads of these spacers receive three flat head screws during the final assembly. If the engagement between the spacer and the Main board is loose before disengaging the flat head screw and the nylon spacer, the bottom housing can not be separated from the slide housing.

However, the Top Housing S/A must go through a calibration for monitoring the battery voltage if the Micro-Controller is replaced. (i.e., software update etc.) The adjustment and the calibration are discussed later in this manual (Tests and Calibration). Some earlier versions of the Top Housing S/A had a trim pot for adjusting the contrast of the display. It is no longer used with current production.

3.4.2 ..... Slide Housing S/A (P/N 1-68-20A02-0-X) (Appendix A) and Slide Housing 2 S/A (P/N 1-68-20A07-0-X) (Appendix A)

The Slide Housing S/A and Slide Housing 2 S/A are the most complex subassembly in the pump. Proper sequence must be followed to assure reliability and efficiency in assembling.

3.4.2.1 Assembling the Plunger Holder/Track S/A (P/N 1-68-20A04-0-X) (Appendix A) and Plunger/Track 2 S/A (P/N 1-68-20A10-0-X) (Appendix A)

To obtain mechanical stability adequate torque must be applied to tighten the reeds onto the plunger holder and the track.

The reeds on the plunger holder must be aligned (perpendicular) to the top surface of the plunger. Note the orientation of the nut plates. The hole of the plates should be biased downward.

Shims must be used to ensure symmetrical gaps between the plunger holder and the track. Note the orientation of the nut plate for holding the screw, the hole should be biased upward. The plunger holder should be free from any mechanical interference from the track.

3.4.2.2 ..... Assembling the Slide Housing S/A (P/N 1-68-20A02-0-X) and Slide Housing 2 S/A (P/N1-68-20A07-0-X)

3.4.2.2.1 ... Assembling the Syringe Clamp etc. to the Slide Housing S/A:

The torsion spring for the syringe clamp gear must not be overtightened since the spring could be damaged permanently when the clamp is lifted up.

Follow the procedure to properly engage the size potentiometer gear with the syringe clamp so that the minimum and maximum positions of the clamp fall within the potentiometer's mechanical range. A final adjustment is needed (see Tests and Calibrations) to bring both positions within the potentiometer's electrical range.

The hardware (clamp, screws) for securing the potentiometer and the torsion spring must be tightened after the calibration. A torque seal must be applied to the screws to discourage tampering.

3.4.2.2.2 ... Assembling the Plunger Holder/ Track S/A to the Slide Housing S/A: and Plunger Track 2 S/A to Slide Housing S/A

EXTREME CAUTION should be exercised during the removal or installation of the Clutch Nuts and the clutch spring. Wear safety eyeglasses because the clutch spring could spring out and cause physical harm to the operator or someone nearby.

The tab at the end of the clutch nuts must be oriented correctly so that the nuts can be properly engaged into the track slot.

The length of the force gauge cable inside the track (or the force cable S/A in the Plunger/ Track 2 S/A) must be closely controlled to avoid any interference due to the rolling movement of the cable inside the track.

For the old or existing force sensor cable of 2001/2010, the bending and termination of the force gauge cable must be carefully handled because the cable copper trace can be broken

very easily by bending it back and forth, especially at the end of the cable. Caution should be taken not to stress these soldering joints (i.e., wires soldered onto the end of the cable) during the removal of the Auxiliary board. For the 2010*i* or pump with new plunger/track 2 S/A, the cable is more resistant to the bending and handling.

3.4.2.2.3 ... Assembling the Position Potentiometer to the Slide Housing S/A:

The hex nut on the potentiometer must be tightened to prevent the potentiometer from turning with the Pot holder.

Make sure that proper timing is followed to engage the Position Potentiometer (pot) gear to the cluster gear (and the track) so that the potentiometer center tab stays within the electrical range at both extreme track positions.
Control the engagement tightness between the pot gear and the cluster gear by adjusting the slot on the pot holder to obtain smooth track movement and minimum backlash between the gears.

The screws for the Pot holder must be secured to avoid mechanical drifting of the pot holder when operating the track.

3.4.2.2.4 ... Assembling the Motor Mount to the Slide Housing:

A special alignment tool must be used for aligning the motor mount bracket to the slide housing to minimize side loading between the worm and the motor shaft. As long as this motor mount bracket has not been disturbed, there is no need to realign if the motor is removed.

3.4.2.2.5 ... Assembling the Leadscrew etc. to the Slide Housing S/A:

CAUTION:

Must be taken to avoid causing burrs to the polished surfaces of the worm, and the leadscrew. Burrs cause a reduction of the overall output torque of the motor / transmission system.

Follow the procedure very carefully when assembling the leadscrew and bearings / bushings into the slide housing. Press the bearing inward to seat the leadscrew and bushing firmly into the housing. After E-clips are installed, press the leadscrew towards the motor to re-seat the washer and the bearing. Check the rotation of the leadscrew. Make sure little friction is detected. Also make sure that no damage is done to the teeth of the worm gear during installation or removal.

3.4.2.2.6 ... Assembling the Auxiliary Board to the Slide Housing S/A:

When soldering the terminal connectors of the force cable , note the polarity of the connectors when they are soldered to the Auxiliary board. The Auxiliary board should have previously been properly checked and preliminarily adjusted.

3.4.2.2.7 ... Assembling the Worm and the Motor to the Slide Housing S/A:

Make sure that a small amount of grease is applied inside the shaft coupler on the worm for reducing motor noise (generated by the motor shaft driver and the coupler) at certain speeds. Also, clean the excess grease on the shaft coupler to minimize contamination (on the markers of the coupler) which might prevent the rotation sensor from properly sensing the motor shaft rotation.

3.4.2.3 ..... Adjustments and Calibrations:

The Slide Housing S/A needs both mechanical and electrical adjustments, as well as final calibrations for the sensors: (Refer to Tests and Calibrations for detailed procedures)

Mechanical adjustments involve setting the timing for both the size and position potentiometers.

Electrical adjustments involve the two trim pots on the Auxiliary board. The pot near the motor is used for adjusting the current for the photodiode to obtain the best rotation signal. The other pot is used to adjust the voltage offset of the force sensor signal when no force is applied to the sensor.

Final calibrations are required for the force, the position, and the size sensors. All calibration information is stored inside the Micro-Controller. Thus, if the Slide Housing S/A is replaced, or the sensors are serviced, then all calibrations need to be performed or checked.

3.4.3 ..... Bottom Housing S/A (P/N 1-68-20A01-0-X) (Appendix A)

The battery pack is secured by double-sided adhesive tape. Since the gap between top of the battery and the underside of the Main board is small, it is very important that the battery pack is pushed down towards the bottom housing as far as possible.

A tool should be used to tighten the ring nut for securing the DIN S/A to the bottom housing. Use an 8-pin strain relief to join the two connectors from the DIN S/A. Note the polarity.

Note the power switch orientation when it is installed into the bottom housing so that the legend on the switch is correctly positioned.

Note the orientation or the polarity of the two 4-pin connectors from the power switch and the battery when they are combined into an 8-pin connector with a strain relief. Use the tie-wrap to obtain a good cable routing.

3.4.4 ..... System Integration (Refer to Appendix A, P/N 1-72-20010-0-1)

The complete system is integrated together by: inserting the Slide Housing S/A into the Bottom Housing S/A, connecting all the cables to the Top Housing S/A, and securing the

three subassemblies together with five (5) flat head screws. Since the space left inside the pump is tight, the following cautions should be exercised to assure reliable pump operation.

Carefully match the tongue and groove between the Slide Housing S/A and the Bottom Housing S/A when putting them together. If an unusual amount of force is needed, it is very likely that the tongue and groove are not lined up properly. Forcing them together could cause damage to the housing.

The cable tie-wrap should be used to assist cable routing and to avoid inserting the connectors into the wrong receptacles. It is very important to follow the factory cable routing so that the cables / wires are not caught in the wrong places. Noticeably, the wires from the battery pack and DIN connector could be pinched between the Main board and the DIN connector if the wires are not bundled together with the cable tie. The Flat ribbon cable between the Main board and the Auxiliary board could be pinched between the battery and the Main board if the cable is not bent in the correct direction. The battery cable could be trapped under the syringe clamp if it is not properly tied to other cables with the cable tie. Observe the original cable routing and cable tie placement before disassembling the cables. Do not force the subassemblies together since this is an indication that there might be some interference caused by the cables.

Through the bottom housing holes and the holes at the legs of the slide housing, three flat head screws are threaded into the long nylon spacers on the Main board of the Top Housing S/A. If the spacers are not tightly threaded into the Main board, they can become loose before the flat head screws can be removed. If this happens, the nylon spacers and the flat head screws prevent the separation of the slide housing and the bottom housing. In this case, continue turning the flat head screws until the Top Housing S/A is separated. Then, using a plier hold the spacer to assist the removal of the flat head screw from the spacer. Do not force the separation between the Slide Housing S/A and the Bottom Housing S/A, because the legs of the slide housing can be broken off. This breakage is very expensive, because the Slide Housing S/A must be completely disassembled in order to replace the slide housing.

If the bottom housing DIN receptacle is loose due to the repeated insertion of the charger plug, the ring nut of the DIN receptacle should be tightened with a tool. Apply some thread lock adhesive. Do not overtighten the DIN connector ring nut (due to the use of the tool). Check by connecting the locking nut on the charger plug into the DIN receptacle. Screw the connector into its full length.

3.5 .....ADDITIONAL DETAILED DISCUSSIONS:

3.5.1.....Motor Power Control

In order to conserve battery energy and prevent overheating the stepper motor, high current must be applied to the motor for a sufficient time period to assure that the stepper motor has advanced to the new position. After that period, the motor current can be cut back to a lower level for holding the motor at the new position. The length of this timing interval varies with the motor type. The pump allows approximately 10ms before switching the motor to a low power setting. By switching the motor to the low power mode, battery power can be

greatly conserved. In other words, if the motor pulse interval is greater than 10ms (i.e., 100 steps per second), high power is applied to the motor for the first 10ms and low power is used for the rest of the motor pulse interval. No energy saving can be realized if the motor is running faster than 100 pulses per second.

3.5.2..... Occlusion Detection

During system calibration, the A/D converter readings for 0LB and 16LB are stored in the Micro-Controller. There is an occlusion force table, in the program area of the Micro-Controller, which stores the occlusion force (in LBs) for any syringe manufacturer and size. This force is converted to a corresponding A/D converter reading from the interpolation calculation with the A/D readings of 0LB and 16LB. This calculated number is the threshold value and is stored in a nonvolatile memory location. The amplified force sensor voltage for the applied force is converted to a digital reading by the A/D converter. This reading is compared with the stored threshold value during the delivery. If the A/D reading is higher, the occlusion alert is triggered. However, if the A/D reading exceeds the threshold within a small window before the syringe empty point, then it is considered an empty syringe condition. An empty syringe alarm is indicated instead of the occlusion alarm. This method is employed to compensate for the non-linearity and tolerance of the size potentiometer.

3.5.3..... Rotation Detection

There are four transitions and 48 motor steps per motor shaft revolution. Thus, in theory, 72 transitions (4*18) should be detected for every 18 motor revolutions (or 864 steps). Due to the rotation sensor resolution, the Micro-Controller expects to see the transition counts between 69 and 75 every time the motor advances 864 steps. Otherwise, the alarm "SYSTEM ERROR U" for under-delivery or "SYSTEM ERROR V" for overdelivery will be signaled.

3.5.4..... Size Sensing

During system calibration, the corresponding A/D readings of the size potentiometer for the known syringe sizes are remembered by the Micro-Controller and stored in nonvolatile memory. There is a size table inside the program area of the Micro-Controller storing a number (proportional to the outside diameter) for each specific syringe manufacturer and size. During the syringe size confirmation, the Micro-Controller takes the size reading of the unknown syringe form the A/D converter and tries to determine the syringe size by searching the size table for the specified syringe manufacturer. If the size reading of the unknown syringe falls within +/- 0.045" (except for 1cc syringes whose tolerance is +/-0.030") of a number in the size table, the size of the unknown syringe will be recognized. If a match can not be found, the "invalid size" alert is given. After a successful recognition, the current size A/D reading is stored in a RAM location which is used for comparison during syringe size monitoring. If the A/D reading of the size sensor deviates significantly from the stored value, the Micro-Controller will indicate that the current syringe has been removed or disturbed. If this condition is detected during delivery, the "Syringe Pops Out" alarm is given. If detected in the stop/program mode, the "Load syringe / press enter" message is given to request the user to again confirm the syringe size.

3.5.5.....Position Sensing

During system calibration, the A/D converter readings for position 0 (POS0, most inward) and position 99 (POS99, most outward) are stored in the nonvolatile memory of the Micro-Controller. The distance between the two positions is 4.836 inches. From the two readings, the Micro-Controller can calculate how many motor steps (STEPN) are required to produce a change in the A/D reading of the position sensor (STEPN=4.836*20*44*48/(POS99-POS0). At any time, the current track position can be monitored by reading the A/D converter for the position potentiometer reading. The Micro-Controller assumes, after advancing 2.5*STEPN motor steps, that the difference in the A/D readings for the two different positions should be 2.5. However, due to the potentiometer non-linearity, and the gearing system backlash, the reading differences can be from 1 to 4. The "Check Clutch" alarm is given if there is no change or too large a change when the motor advances the predetermined number of steps. Thus, if the track fails to drive the syringe plunger due to a broken gearing system, broken clutch, or if the track is manually moved, the condition is detected by the position sensor.

The Position sensor is also used to signal the empty syringe alarm. There is a table (EMPTB), inside the Micro-Controller program area, which stores the track position for each syringe manufacturer and size when the syringe is empty. During the calculation, the syringe empty position is converted to a corresponding A/D reading (stored in EMPCNT) by interpolating the A/D readings of position 0 and 4.836. If the current position sensor reading is less than EMPCNT, the alarm for an empty syringe is given. This empty syringe alarm is also indicated if an occlusion condition is detected while the current position is between 0.150 inches and the theoretical empty position. This approach compensates for the non-linearity and the position sensing system variation.

3.5.6.....Delivery Accuracy

As described above, the array of sensors are used mainly to confirm proper pump behavior during delivery. The absolute delivery accuracy depends on three factors: the system clock, the accuracy of the leadscrew, and the correct software. All these factors do not need calibration and do not wear with time and usage. A rigorous validation process before the software release, and the program integrity test during the system self test at power-up eliminate error due to the software program. The error in the system clock is negligible. The majority of the error is attributed to the leadscrew tolerance. This tolerance is less than 0.4%.

SECTION 4. MAINTENANCE

4.1 .....INTRODUCTION

This section discusses general pump maintenance including procedures for tests and calibrations. A performance test procedure is included in Appendix D which can be used as part of a routine preventive maintenance schedule. The test equipment required for performance tests and calibration procedure is indicated in each respective procedure.

4.2 .....PREVENTIVE MAINTENANCE

A routine preventive maintenance schedule should be followed according to the policy defined by the individual hospital. Presently, Medex recommends that these procedures be performed at least once every six months. Additional routine cleaning and inspections should be performed on an as needed basis (i.e., droppage, fluid contamination, suspect malfunction, etc.).

4.2.1.....Performance Test

The performance test procedures in Appendix D can be used as a reference for preventive maintenance pump testing. As discussed in previous sections, the pump's delivery accuracy does not require adjustment or calibration, and does not change with wearing caused by normal usage. The accuracy does not rely on the sensors. The sensors are used for confirmation only. Thus, the flow rate accuracy is maintenance-free. However, the sensors must be checked periodically or as often as necessary to prevent false alarms. If the sensors fail to meet the specifications, any calibration should only be performed by qualified personnel. The calibration procedures should be carefully followed. Otherwise, the pump will not perform properly. Also, the disassembly /assembly procedures should be followed when pump repair is needed.

4.2.2 Cleaning and Miscellaneous:

Cleaning is performed as part of a disinfection procedure or to remove contamination due to inadvertent spill. However, the chemical used to clean the pump should be carefully selected because some chemicals attack and weaken the pump's plastic housing.

The pump housing may be cleaned with the following agents (list updated periodically):

1. **CIDEX** *(by Johnson & Johnson Medical, Inc.)*
2. **CLOROX (and 95% water)**
3. **COLD SPOR***(by Medrex Research Corporation)*
4. **ENVY** *(by S. C. Johnson & Son, Inc.)*
5. **ENZOL** *(by Johnson & Johnson Medical, Inc.)*

6. **ISOPROPYL ALCOHOL (70% - undiluted)**
7. **MANU-KLENZ** *(by Calgon Vestal Laboratories)*
8. **METRI-ZYME** *(by Metrex Research Corp.)*
9. **MILD SOAP AND WATER SOLUTION**
10. **NUTRA-pH** *(by Snowden-Pencer)*
11. **SANI-CLOTH** *(by Distributor: Professional Disposables, Inc.)*
12. **SEPTISOL** *(by Calgon Vestal Laboratories)*
13. **SPORICIDIN** *(by Sporicidin International)*
14. **STAPHENE, se** *(by Calgon Vestal Laboratories)*
15. **TINCTURE OF GREEN SOAP**
16. **TOR-II** *(by Huntington Laboratories, Inc.)*
17. **WHISK ADHESIVE REMOVER PAD** *(by Baxter Healthcare Corp.)*

CAUTION:

Recommendations for agents applies to compatibility of agent with the plastic housing and is not based on the cleansing/disinfecting ability or effectiveness. Medex makes no representations as to any agent's ability to cleanse or disinfect. We defer to the guidelines of the manufacturer for mixing instructions for agents listed.

WARNING:

Do not use solutions containing strong detergents, organic solvents, quarternary ammonium or ammonium chloride to clean any portion of the pump, as serious damage could result. **DO NOT IMMERSE.** Avoid spills and inadvertent allowance of fluid in the pump housing.

The pump is designed to RESIST fluid entry. However, it is NOT WATER-PROOF. Do not apply excessive cleaning agents. Remove residue agent as soon as possible, and immediately clean the pump following accidental contamination.

There are several moving parts in the pump. Efforts should be made to avoid hindering the operation of these parts (e.g. adhesive tape etc). For examples:

- Syringe Clamp: a smooth sliding operation of this part is very important for size recognition and to ensure proper seating of the syringe. Do not apply any tape or adhesive material on the clamp's sliding surface. Try to keep the sliding surface as clean as possible. If the sliding of the clamp becomes sluggish, it can be improved easily by applying a very small amount of silicon lubricant (such as Dow Corning 111 Valve Lubricant & Sealant) on its sliding surface.

- The track must be able to move in and out easily when the clutch nut is disengaged by the clutch lever. Do not apply any chemical which might bond the track to the slide housing. Refer to Drawing 1-68-20A02-0-X. Pay special attention to the underside of the track assembly (bubble #2) and the row of plastic teeth that mesh with the track cluster gear (bubble #8) in the middle of the track channel. Using a generous amount of isopropyl alcohol or soap and water, clean the track channel, track teeth and cluster

gear using a toothbrush or dental pick to break loose the heavy, dried or caked on contamination. Then rinse and dry channel by moving the track assembly back and forth and wiping away the excess cleaning solution.

Be careful not to use a sharp object which might damage the track teeth or the cluster gear. Damage to the teeth on either assembly will result in the pump not sensing track movement and giving a check clutch alarm.

Although the housing of the pump is made of high impact resistant polycarbonate, dropping the pump can cause breakage or chipping. Care should be taken in handling the pump during transportation.

4.3 ..... DISASSEMBLING THE PUMP

CAUTION:

1. It is very important that the person disassembling the pump observe full ESD precautions and perform the work at an ESD safe work station to avoid possible electrostatic discharge (ESD) damage to the electronic components.

2. We recommend that the person(s) responsible for repairing the pump should attend training class available by Medfusion to familiarize himself/herself with the details of disassembling and assembling the pump so that the reliability and the performance of the pump can be assured.

3. As a general rule, 4-40 screws are torqued to 16 oz-inch and 2-56 screws are torqued to 10 oz-inch.

Turn the pump off. Remove the charger connector. Remove the pole clamp or pole clamp plate by removing the two flat head screws. Remove the five (5) flat head screws which hold the major subassemblies of the pump together. One of the screws is covered with a tamper-proof label.

4.3.1 ..... Disconnect the Cables from Sub-Assemblies:

Note the cable routing, the polarity and the positions of the connectors. The pump can now be separated into three major subassemblies: Top Housing S/A, Bottom Housing S/A, and Slide Housing S/A.

4.3.2 ..... Disassembling the Top Housing S/A:

Remove the three long spacers and three screws. The Top Housing S/A can be further disassembled into the Main board S/A and the Top housing. The LCD display can be removed from the Top Housing by removing two brass spacers. The Micro-Controller can be removed from the socket of the Main board. The internal fuse can be replaced by de-soldering it from the Main board.

4.3.3.....Disassembling the Bottom Housing S/A:

The Bottom Housing S/A can be further disassembled into the DIN connector S/A, Power switch S/A, Alarm S/A, Battery S/A, and the Bottom Housing, by disengaging the securing hardware and cable ties. **Note the cable routing and the positioning of the cable ties.** The battery S/A can only be removed by cutting off the adhesive tape between the battery pack and the bottom housing with a knife. The Power switch S/A along with the switch guards can be pulled out of the bottom housing by depressing the clips on the switch. The connectors for the battery S/A and power switch can be separated by removing the joint strain relief. Note the power switch green wire is always located at the most outside position.

CAUTION:

Note the two screws for the alarm should be torqued to 10 oz-inch.

4.3.4 Disassembling the Slide Housing S/A:

The Slide Housing S/A is the most complex subassembly. Disassembling the Slide Housing S/A by the user is **NOT RECOMMENDED.** However, the following descriptions describe replacing particular parts in the Slide Housing S/A. The User should understand the pump in depth before attempting to service this subassembly.

NOTE: *For complete assembly instructions, refer to drawings and procedure in Appendix A.4 or A.7.*

CAUTION:

The mechanical stop for the syringe sizing clamp is located on the bottom housing S/A. With the bottom housing separated from the slide housing S/A, it is possible to pull the syringe clamp out of the slide housing S/A, possibly damaging the syringe size sensing potentiometer.

4.3.4.1.....Replacing Motor S/A or the Worm:

The removal of the motor and the worm can be done by removing the supporting bracket and hardware for the motor. **IMPORTANT: DO NOT** loosen the two brass spacers holding down the motor alignment bracket underneath the motor. If the motor alignment bracket is disturbed, a special alignment tool is required.

4.3.4.2.....The Position Sensor:

The position sensor can be detached from the Slide S/A by removing the two holding screws and the Auxiliary board connector. The difficult part in reassembly is to ensure that proper timing between the potentiometer spur gear and the cluster gear is maintained.

4.3.4.3.....Size Sensor:

The size potentiometer, gear, spring, and syringe clamp can be disengaged by removing the four (4) holding screws. However, the difficulty in reassembly is to ensure that proper timing between the potentiometer gear and the gear rack on the clamp is maintained. Also, the pre-loading amount for the torsion spring must be properly adjusted. Removal of the position sensor might be necessary in order to apply proper pre-loading of the torsion spring.

4.3.4.4 .....Auxiliary Board:

To remove the Auxiliary board, three (3) terminals connecting the force sensor cable to the Auxiliary board must be de-soldered first. Then the size and the position potentiometer connectors must be disconnected. Remove the two holding screws to disengage the Auxiliary board from the Slide S/A. Note the trim pots on the Auxiliary board must be adjusted if the force sensor is replaced. Adjustment of the photodiode current is needed only if the rotation sensor on the Auxiliary board is replaced.

4.3.4.5.....Replacing the Worm Gear and the Leadscrew:

The E-clips on both ends of the leadscrew must be removed first. The leadscrew can be removed by opening the clutch nuts with the clutch lever and pushing the leadscrew from the clutch lever end toward the direction of the motor. Remove the worm gear with a proper tool. **DO NOT** damage the worm gear teeth. The leadscrew, bushing, and bearing can now be removed while the clutch nuts are opened. Handle the leadscrew with care. **DO NOT** damage the threads. Proper reassembly procedures must be followed to obtain a specified gap so that the rotation of the leadscrew is free from any binding.

4.3.4.6.....Disengaging the Track S/A from the Slide S/A:

The size sensor, Auxiliary board, and leadscrew must be removed first. Move the track to the most extended outward position and turn over the Slide S/A so that the bottom of the track faces upward. Remove the clutch actuator rod cover by removing the two (2) holding screws. Sightly move the clutch actuator rod inward to disengage the actuator rod from the clutch lever. Swing the lever 90 degrees so that it can be removed from the track. The clutch actuator rod can then be pulled out. Remove the clutch key next to the clutch nuts by pulling it out with a plier. The clutch nuts can then be removed by pulling them sideways and forward. **CAUTION** should be exercised when removing the clutch nuts from the Slide S/A because of the clutch spring. Remove the double sided tape for the force cable underneath the slide housing. The track S/A can then be disengaged from the slide housing.

4.3.4.7.....Disassembling the Plunger Holder S/A from the Track S/A:

To disengage the force sensor / plunger holder from the track, remove the socket head screw visible through the clutch lever hole. A threaded nut plate will fall off. After the plunger holder S/A is pulled out of the track, the force sensor can be removed from the plunger holder by removing the holding socket head screw. Two plates (one with threads) will fall off.

4.4 ..... TESTS AND CALIBRATIONS

4.4.1 ..... Tests

There are many test levels at different assembly stages: Board level, Subassembly level, and Final system level. Board level tests are performed by Medex. The subassembly level tests are required after a subassembly has been taken apart. Special tools and fixtures are needed to perform these tests. Refer to Medex Production Testing Procedure available upon special request.

The final system level can be tested by following the Performance Tests in Appendix D. The sensor calibrations can be checked using the QC inspection mode described in the following sections.

4.4.2 ..... System Calibrations:

The pump provides a Calibration Mode for handling the inspection and the calibration of the sensors. There are different levels of calibrations: Battery Calibration, Sensor Calibration, and QC inspection. The Sensor calibration as well as the QC inspection can be performed by the user when the pump is completely assembled. However, the battery calibration can only be performed at the Top Housing S/A level. The adjustment requires a special test fixture and is performed at Medex. The battery calibration is needed only when the Micro-Controller on the Main board is replaced. Under normal condition, there is no need for further adjustment. Thus, the procedure for the adjustment is not discussed in this section. It is available upon special request.

The system calibration mode can be accessed by pressing and holding the stop/program key and the select key while turning on the pump. When released, the Micro-Controller displays "LOCK--->" and waits for a valid access code to be entered.

4.4.2.1 ..... Sensor Calibration:

This calibration mode can be accessed by entering code "8021" for the model 2001 and 2010 or "0202" for the model 2010*i*. This mode is used for calibrating the force sensor, position sensor, and size sensor.

During each calibration stage, the enter key is used to instruct the Micro-Controller to accept the A/D reading for the calibration point. The program key is used to skip the current calibration stage. All other keys can be used to go back to the previous calibration point.

- **Force Sensor Calibration:**
  There are three stages: 0LB calibration, 16LB calibration, and the force sensor calibration test.

  0LB calibration:
  The Micro-Controller displays "ADJ. FORCE 00LB=XX" where XX is the A/D reading

for the amplified force sensor voltage. The operator should make sure that there is no force being applied to the plunger holder. For the Track-2 assembly put a .035 inch or greater shim into the plunger retainer and release the clutch lever. Press the enter key to instruct the Micro-Controller to store the current A/D reading for the 0LB force. The A/D reading for the 0LB force should be between 0D and 15. If an A/D reading is out of this range, then the variable resistor VR2 (near the size pot) on the Auxiliary board needs to be adjusted until this range is obtained.

16LB calibration:
After the 0LB force is calibrated, the Micro-Controller displays "ADJ. FORCE 16LB=XX", where XX is the A/D reading for the applied force sensor voltage and waits for the operator's response. The operator should use a special force gauge fixture to apply 16LB force to the plunger holder. Press the enter key to instruct the Micro-Controller to store the A/D reading for the 16LB force. Special force gauges can be purchased from Medfusion, Inc.

Force sensor calibration test:
After the 16LB force calibration, the Micro-Controller displays "FORCE(LB) Y.YYY =XX" where Y.YYY is the calculated force reading in pounds and XX is the A/D reading for the force sensor. The Micro-Controller continuously takes the A/D reading from the force sensor and converts the reading to a force reading in pounds. The conversion is done by using the interpolation calculation based on the two pre-calibrated readings for the 0LB and 16LB. The operator should apply different forces to the plunger holder and verify that the displayed force reading falls within the acceptable range.

- **Position Sensor Calibration**
There are three stages POS. 0 calibration, POS. 99 calibration, and Position sensor calibration test:

POS. 0 calibration:
After pressing the enter key to exit the force sensor calibration, the Micro-Controller displays "ADJ. POS. 00=XX" where XX is the A/D reading for the current track position. The operator should move the track to the most inward position, making sure to pull syringe clamp out of the way of plunger retainer, do not release the clutch lever, and press the enter key. If the clutch lever is released prior to pressing the enter key, the engagement of the clutch nut and the leadscrew might change the A/D reading. The Micro-Controller stores this A/D reading as POS 0.

POS. 99 calibration:
Then the LCD displays "ADJ. POS. 99=XX" where XX is the A/D reading for the current track position. The operator moves the track to the most extended position and presses the enter key while holding the clutch lever open. The Micro-Controller stores this A/D reading for POS. 99. The displacement between the two points is 4.836 inches. O position should be between O6 and 18 and fully open is less than FA.

Position sensor calibration test:
The LCD displays "POS. (INCH) Y.YYY=XX" where XX is the A/D reading for the current track position and Y.YYY is the calculated position (in inches) corresponding to the A/

D reading. The formula is: Y.YYY=(ADC-AD0) X 4.836/(AD99-AD0) ; where AD0,AD99, and ADC are the A/D readings for POS.0,POS.99, and the current position.

- **Size sensor calibration:**
  There are five stages: 4 calibration stages for TERU 1, TERU 6, TERU 25, TERU 60, and Size sensor calibration test:

  Size calibrations with TERUMO syringes 1cc, 6cc, 25cc, and 60cc:
  After pressing the enter key to exit the position sensor calibration, the Micro-Controller displays "TERU SIZE 01=XX" where XX is the A/D reading for the size sensor. By lifting up and then releasing the syringe clamp several times, it can be seen that the A/D reading varies slightly from time to time for the same syringe due to the syringe clamp tension applied by the torsion spring. The most common reading should be used as the calibration reading. The operator should now correctly load TERUMO 1cc syringe. Press the enter key to instruct the Micro-Controller to use the most common A/D reading for the syringe. Continue this process for obtaining the calibrated A/D readings for TERUMO 6cc, 25cc, and 60cc syringes. These calibrated A/D readings are stored in the Micro-Controller nonvolatile memory.

  Size sensor calibration test:
  The Micro-Controller displays "SIZE(INCH) Y.YYY=XX" where Y.YYY is the calculated size for the corresponding A/D reading XX. Y.YYY is derived from the interpolation of the current A/D reading with the stored calibrated A/D readings of the 4 TERUMO syringes to compensate for the size sensor's non-linearity. The user should sequentially load the four TERUMO syringes and inspect the size sensor calibration. Refer to the size recognition data sheet in the attached procedure (Appendix D).

  The reason for using TERUMO syringes for size calibration is the TERUMO 60cc syringe has the largest outside diameter (O.D.) when compared to B-D or Monoject syringes. These four syringe sizes were selected to evenly spread the calibration points over the entire range of the size sensor.

4.4.2.2..... QC Inspection:

The QC inspection access code is "100.0" (005.0 for Model 2010*i*). This mode allows the QC inspector to verify the calibration of all sensors without inadvertently modifying a calibration parameter and altering the system calibration.

- **Force sensor calibration test:**
  Once the correct QC access code is entered, the Micro-Controller displays "FORCE(LB) Y.YYY=XX". The operator can use the force gauge fixture to apply a known force to the plunger holder. Compare the force gauge readings with the LCD display readings. If the two readings are within the acceptable range, press the enter key to advance to the Position sensor calibration test. Several different force levels should be tested.

- **Position sensor calibration test:**
  The LCD displays "POS.(INCH) Y.YYY=XX". XX is the A/D reading in Hex code. Y.YYY is the calculated track position in inches. Hold down the clutch lever, move the track

to its most inward position and to its most extended positions. Observe the readings on the LCD display. Two readings "0.000+/-0.005" and "4.836+/-0.005" should be obtained. Record the corresponding hex readings of these two points. Move the track to both end positions, the hex codes displayed on the LCD should be within +/- 1 hex digit of the recorded hex codes. Press the enter key to advance to the size sensor calibration test.

- **Size sensor calibration test:**
  The Micro-Controller displays "SIZE(INCH) Y.YYY=XX". Y.YYY is a size height measurement (in inches) for the syringe to be measured. If no syringe is loaded, the nominal height is 0.100". Correctly load TERUMO 1, 6, 25, and 60 syringes. Verify the readings on the LCD display. Refer to data sheet in Appendix D for the acceptable range for each syringe.

4.5 ..... BATTERY CHARGING

As a convenience, if unit it plugged into AC power, the battery is automatically charging regardless of unit being on/off. With the unit plugged into AC power, press and hold both the stop/program and deliver keys, then turn the pump on. Allow the unit to charge for 16 hours. The unit's battery should achieve 8.2v.

4.6 ..... OCCLUSION SENSING

The Medfusion 2000 series syringe pumps can operate at variable sensitivities to occlusion. The occlusion sensitivity set at the manufacturer (unless otherwise specified) is normal. Three other options exist for the force setting including "LOW", "MID", and "HIGH" in 2001/ 2010 software versions through 1.4 and 1.2 respectively. Choices on 2010*i* are "LOW", "INT", "NORMAL" and "HIGH". The best options may be selected for the specific clinical application. Software for the 2001 after version 1.4 and software after 1.2 version for the 2010 wil have the same occlusion sensitivity as the 2010*i*. "LOW" is 6 psi and "INT" is 10 psi.

To change the force setting on the 2000 series syringe pumps follow these steps:

Step 1:
To enter a different force the 2000 series syringe pump must be fully programmed for a delivery mode and left or placed in the program mode.

Step 2:
Press at the same time the STOP/PROGRAM and ENTER keys, then release. For the 2010

the last line of the LCD will state <sel>/<ent>:Stand-by. Press SELECT and LCD displays <sel>/<ent>:PSI-Adj. Press ENTER. For the 2001 the last line of the LCD will state PSI SETTING = NORM, INT or LOW, MID, HIGH depending upon the previous settings and the pump model and software version.

Step 3:
Use the SELECT key to change the force setting (e.g., NORM, LOW, MID, HIGH) press ENTER to program the desired force table.

If LOW, MID, HIGH are selected the syringe size will be followed by an L, M, H respectively so the operator will be able to identify the proper force table.

The PSI setting is theoretically derived. Generally the actual PSI will be lower than the theoretical value. The actual output pressure is affected by a multiplicity of factors including syringe size, friction between syringe barrel and plunger, catheter gauge, internal diameter of the tubing, durometer of the tubing, residual volume of tubing, rate of infusion, use of various in line devices including stop cocks/filters/valves, etc.

For example, making changes to the force setting with use of a Monoject 35cc syringe affects the following:

Monoject 35cc syringe: (Model 2001/2010)

Normal	11.0 force (lbs)	16.0 max theor psi
Low	6.875 force (lbs)	10.0 max theor psi
Middle	13.75 force (lbs)	20.0 max theor psi
High	15.0 force (lbs)	21.8 max theor psi

Monoject 35cc syringe: (Model 2010*i*)

Normal	11.0 force (lbs)	16.40 max theor psi
Low	4.0 force (lbs)	5.96 max theor psi
Intermediate	6.88 force (lbs)	10.2 max theor psi
High	15.0 force (lbs)	22.30 max theor psi

For further information on theoretical values for other syringe sizes/settings, please contact Medfusion's Technical Services.

4.7 ..... TROUBLE-SHOOTING GUIDE

The Troubleshooting Chart in the Appendix F can be used as a guide to help locate the probable cause of a problem. The chart is not all inclusive, and the causes of some problems may be multiple or not in the chart. The success of the troubleshooting depends largely on the user's knowledge and experience with the pump. Please call the Service Department at Medfusion if further assistance is needed.

4.8 SERVICE AND LIMITED WARRANTY

LIMITED WARRANTY:

MEDEX, INC. warrants to the purchaser that the Syringe Infusion Pump shall be free from defects in material and workmanship for a period of one (1) year from the date of purchase. **MEDEX'S** sole obligation with respect to any such defect is limited to the repair, or at **MEDEX'S** option, replacement of the Syringe Infusion Pump. Purchaser pays return freight charges.

This limited warranty is made on the condition that prompt notification of a defect is given to **MEDEX,** within the warranty period, and that **MEDEX** shall have the sole right to determine whether a defect exists.

This limited warranty does not apply to Syringe Pumps that have been partially or completely disassembled, altered, subjected to misuse, negligence, or accident; or operated other than in accordance with the instructions provided by **MEDEX.**

While under this limited warranty, **MEDEX** recommends that the pump NOT be opened by personnel other than **MEDEX** without consent from **MEDEX'S TECHNICAL SERVICE DEPARTMENT** as this shall be considered un unauthorized repair. Only personnel who have completed the **MEDEX SERVICE SCHOOL** may perform authorized service on **MEDFUSION SYRINGE INFUSION PUMP(S).** An unauthorized repair shall cause this limited warranty to be void. **MEDEX** shall have the sole right to determine whether a repair is authorized.

This limited warranty represents the exclusive obligation of **MEDEX** and the exclusive remedy of the purchaser regarding defects in a Syringe Infusion Pump. **THIS WARRANTY IS GIVEN IN LIEU OF ANY EXPRESS OR IMPLIED WARRANTIES, INCLUDING THE WARRANTY OF MERCHANT-ABILITY OR FITNESS FOR A PARTICULAR PURPOSE.** No person is authorized to modify, in any manner, MEDFUSION'S obligation as described above.

MEDEX reserves the right to make changes in or additions to pumps manufactured and/or sold by **MEDEX** at any time, without incurring any obligation to make the same or similar changes on pumps previously manufactured or sold by **MEDEX. MEDEX** may at its discretion, provide such changes or additions to products at a fee deemed reasonable by **MEDEX.**

SERVICE:

Other than cleaning, maintenance must be performed by qualified biomedical personnel at the institution or at manufacturer. For questions on repair, service or maintenance of our pumps, please call our **TECHNICAL SERVICE DEPARTMENT at 1-404-623-9809.**

CAUTION:

The 2000 series syringe pump should not be serviced by any personnel who have not attended the 2000 Series Service School.

When returning a pump for service, please consider the following:

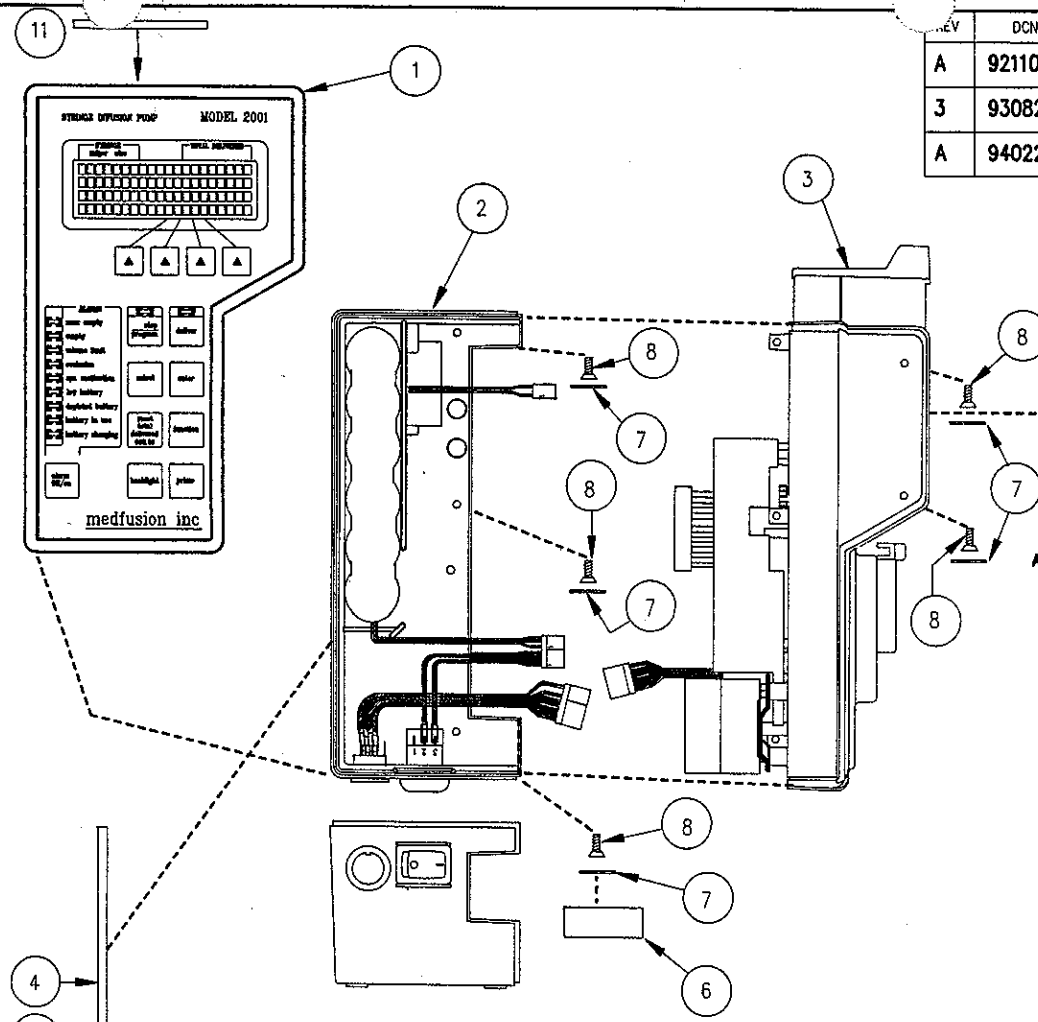
- Call Technical Services at 1-404-623-9809 to obtain a RETURN AUTHORIZATION (will need serial number, model number, P.O.#, other pertinent information related to the reason for return).
- Decontaminate the pump or accessory prior to returning to the manufacturer (according to O.S.H.A. guidelines).

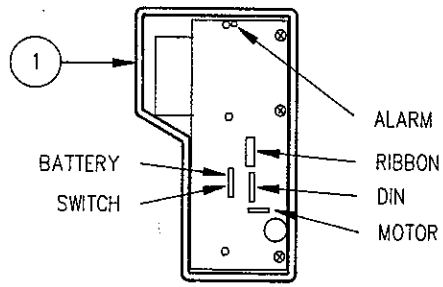
NOTE: *If OSHA guidelines are not followed, original packaging cannot be returned.*

- Package unit in original packaging or other appropriately protective shipping container.
- Indicate the Return Authorization Number on the outside of the packaging.
- Ship to MEDEX via preferred method (at your cost). Indicate preferred method of return.

APPENDIX A.
ASSEMBLY DRAWINGS

REV	DCN#	DESCRIPTION OF REVISION	APPROVED	DATE
A	92110401	ADDED GERMAN LABELS	C. LEE	12-1-92
			L. KUSHNER	12-8-92
3	93082601	ADDED DEVICE TRACKING LABEL	C. LEE	8/27/93
			L. KUSHNER	8/27/93
A	94022401	ADD ESD LABEL	C. Lee	3/1/94
			D. Parker	3-4-94





PC BOARD CONNECTIONS

ASSEMBLY INSTRUCTIONS:

1. PLUG IN CONNECTORS FROM BOTTOM HOUSING (2) TO PCB ON TOP HOUSING. CONNECT ALARM TO PCB ON TOP HOUSING. CONNECT MOTOR AND RIBBON CABLE TO PCB ON TOP HOUSING.
2. ASSEMBLE SLIDE HOUSING SUB ASSEMBLY (3) TO TOP HOUSING SUB ASSEMBLY AND THEN ASSEMBLE INTO BOTTOM HOUSING SUB ASSEMBLY. BE SURE ROUTING WILL NOT INTERFERE WITH ASSEMBLY.
3. INSERT THREE SCREWS (8) FOR THE BOTTOM HOUSING STARTING WITH THE OUTSIDE SCREWS.
4. INSERT THE OTHER TWO SCREWS (8) INTO THE SLIDE HOUSING.
5. TIGHTEN ALL SCREWS.
6. PLACE SCREW HEAD COVERS (7) AND THE TAMPER RESISTANT LABEL (6) OVER SCREW HEAD HOLES.
7. PLACE INSTRUCTIONS (4) ON SIDE OF PUMP FOR 2001, OR (10) FOR 2010G. PLACE SYRINGE RETAINER LABEL (5) ON SIDE OF SLIDE HOUSING S/A FOR ALL 2001 & 2010, OR LABEL (9) FOR 2001G & 2010G.
8. PLACE DEVICE TRACKING LABEL (11) ON THE TOP OF THE BOTTOM HOUSING.

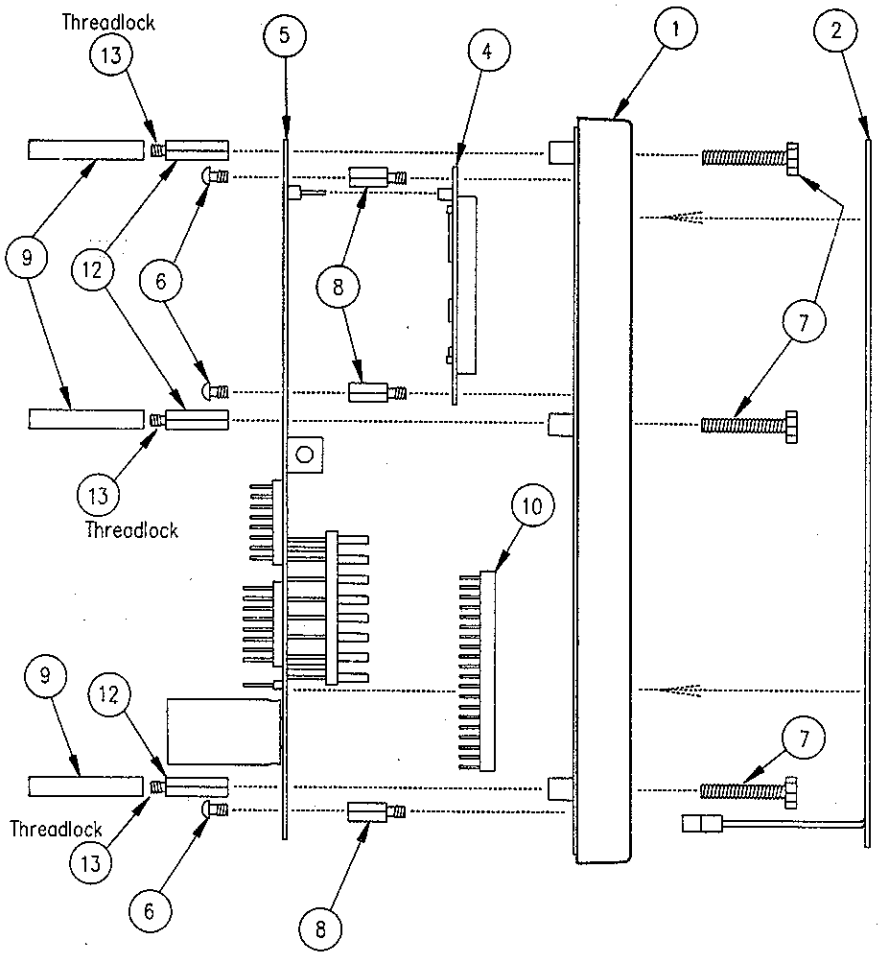
ATTENTION OBSERVE PRECAUTIONS FOR HANDLING ELECTROSTATIC SENSITIVE DEVICES

medexinc

Final Assembly

Part No. 1-7-2-20010-0-2

REV	DCN #	DESCRIPTION OF REVISION	APPROVED	DATE
2C	92011702	ADD STATIC SHIELD BAG	D. AMMANN	3/26/92
			L. KUSHNER	4/14/92
2D	92070805	REWORD STEP 4	C. LEE	9/11/92
			L. KUSHNER	9/22/92
2E	93030906	ADD ESD LABELING	Chi Lee	4/26/93
			[signature]	4-30-93



ATTENTION
OBSERVE PRECAUTIONS FOR HANDLING ELECTROSTATIC SENSITIVE DEVICES
BA20 Printed by LABELMASTER, CHICAGO, IL 60646

ASSEMBLY INSTRUCTIONS:

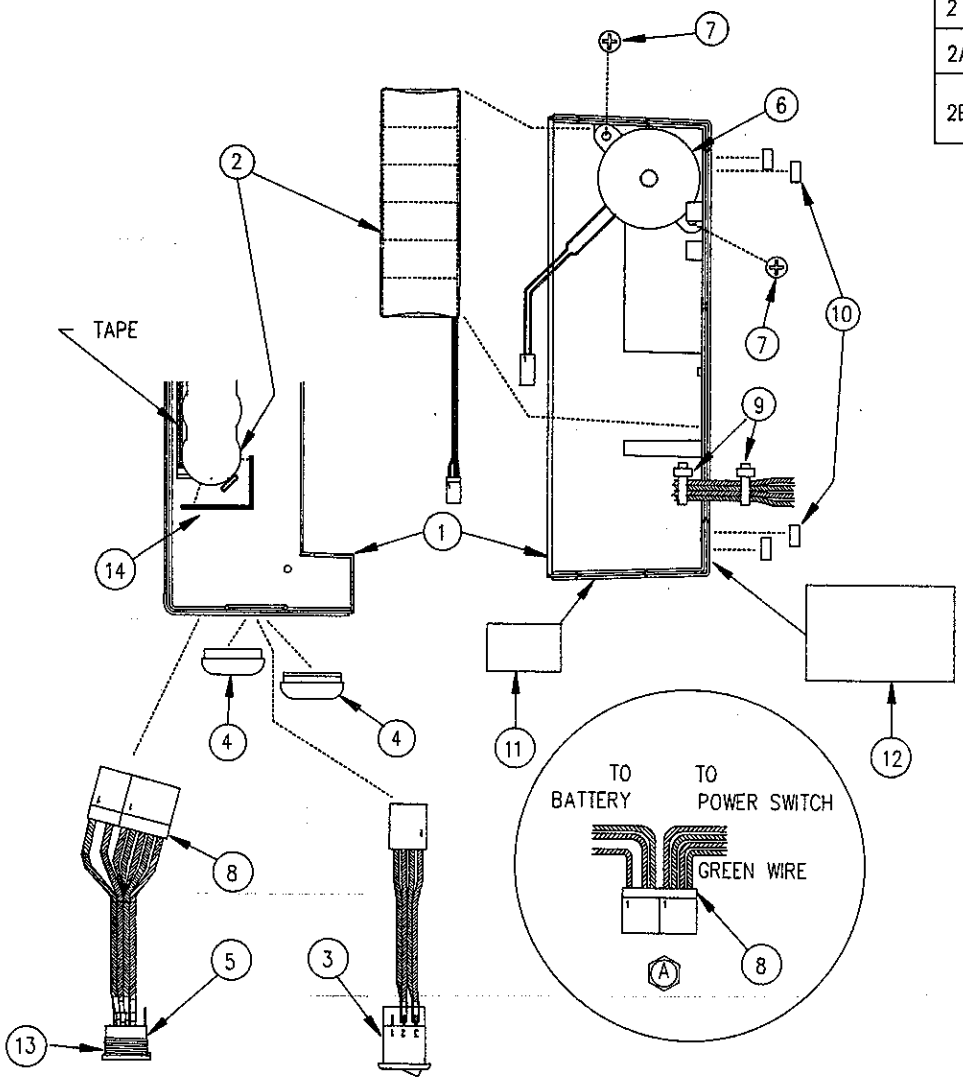
* CAUTION: ASSEMBLY OPERATIONS MUST BE COMPLETED AT AN ESD PROTECTED WORK STATION

1. INSERT 3 HEX HEAD SCREWS IN TOP HOUSING
   REMOVE BACKING FROM KEYPAD AND INSTALL IN TOP HOUSING
   NOTE: IF SEIKO DISPLAY IS TO BE USED,
   TRIM KEYPAD/TOP AROUND LCD DISPLAY
2. INSTALL LCD INTO TOP HOUSING.
3. INSTALL THREE MALE–FEMALE STANDOFFS
4. VERIFY PROGRAMMED MPU IN PLACE ON MAIN PC BOARD
5. CONNECT KEYPAD TAIL TO MAIN PC BOARD
   INSTALL MAIN PC BOARD TO TOP HOUSING S/A
6. INSTALL THREE ROUND NYLON FEMALE STANDOFFS TO THREE BRASS HEX STANDOFFS WITH THREADLOCK. INSTALL ASSEMBLY TO HEX HEAD SCREWS. INSTALL PAN HEAD SCREWS.
7. PLACE IN STATIC SHIELDING BAG & SEAL

medexinc

Top Housing S/A
Part No. 1-68-20A00-0-2

REV	REF	DESCRIPTION OF REVISION	APPROVED	DATE
2	91042504	REVISED ASSEMBLY INSTRUCTIONS	D. AMMANN	5-31-91
			R. BOOTH	6-10-91
2A	91073003	ADDED TAPE (14)	C. LEE	8-14-91
			R. BOOTH	8-16-91
2B	93010803	REVISED ASSEMBLY PROCEDURE TO ADD HYPERTRONICS ASSEMBLY INSTRUCTIONS.	Chris Lee	2/3/93
			[illegible]	2-4-93



ASSEMBLY INSTRUCTIONS:

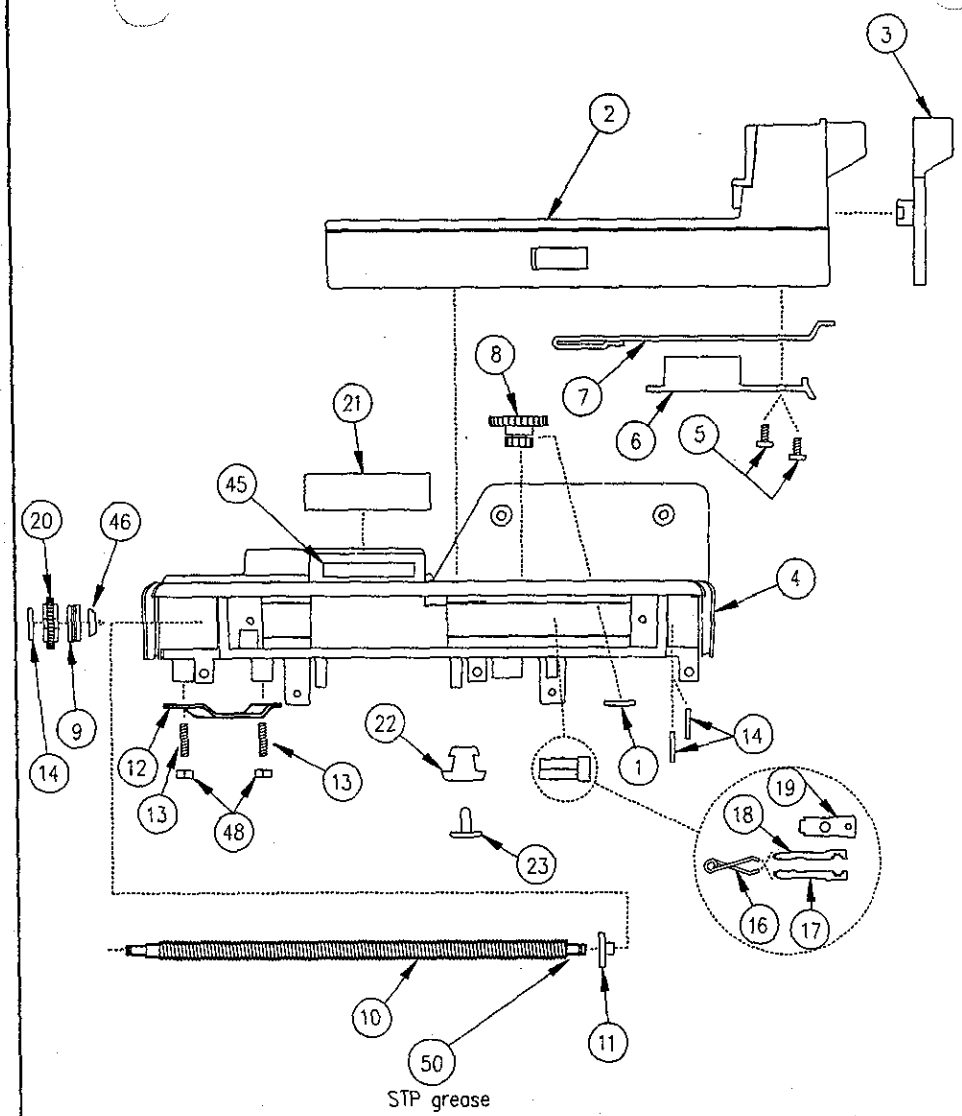
1. ATTACH TWO SWITCH GUARDS (4) TO BOTTOM HOUSING.
2. INSTALL HIRSCHMANN DIN RECEPTACLE SUB-ASSEMBLY OR HYPERTRONICS CABLE SUB-ASSEMBLY (5) THROUGH THE BOTTOM HOUSING. NOTE THE LOCATING TAB.
   FOR HIRSCHMANN ONLY;
   ADD A SMALL AMOUNT OF LOCTITE (13) TO THE THREADS. ATTACH THE RETAINING RING TO THE DIN RECEPTACLE WITH THE NOTCHES TOWARDS THE CENTER. TIGHTEN WITH THE SPECIAL TOOL.
   FOR HYPERTRONICS ONLY;
   SECURE THE CONNECTOR WITH THE TUBE NUT FROM THE INSIDE. THE FLATS OF THE NUT GO TOWARDS THE OUTSIDE OF THE HOUSING. DO NOT OVERTIGHTEN THE NUT.
3. PRESS POWER SWITCH (3) INTO BOTTOM HOUSING. BE SURE THAT THE O (OFF) POSITION OF THE SWITCH IS CLOSEST TO THE DIN RECEPTACLE.
4. PEEL OFF TAPE BACKING ON BACK OF BATTERY PACK (2), AND PLACE INTO BOTTOM HOUSING WITH CABLE ON BOTTOM OF BATTERY PACK. COVER BATTERY PACK WITH PROTECTIVE TAPE (14) AS SHOWN.
5. ATTACH ALARM (6) TO BOTTOM HOUSING (1) WITH 2 SCREWS (7), TIGHTEN TO 16 IN-OZ.
6. ADD STRAIN RELIEF (8) TO THE THE POWER SWITCH AND BATTERY CONNECTOR (BE SURE GREEN WIRE IS ON THE OUTSIDE). ADD STRAIN RELIEF (8) TO THE TWO DIN CONNECTORS.
7. USE 2 WIRE TIES (9) TO TIE THE WIRES FROM THE POWER SWITCH, DIN RECEPTACLE AND BATTERIES TOGETHER.
8. ADD FOUR FEET (10) TO BOTTOM HOUSING IN RECESS PROVIDED.
9. ADD LABELS (11) & (12)

medexinc

Bottom Housing S/A

Part No. 1-68-20A01-0-2

REV	DCN#	DESCRIPTION OF REVISION	APPROVED	DATE
5A	91060302	SAFETY WARNING ADDED	D. AMMANN	6/14/91
			R. BOOTH	6/14/91
6	91070802	NEW FORCE CABLE AND MOTOR BRACKET. REMOVE INSTRUCTIONS FROM DWGS.	C. LEE	7/23/91
			R. BOOTH	7/24/91
6A	93030906	ADD ESD LABELING	R Rush	6/8/93
			C Lee	6/9/93

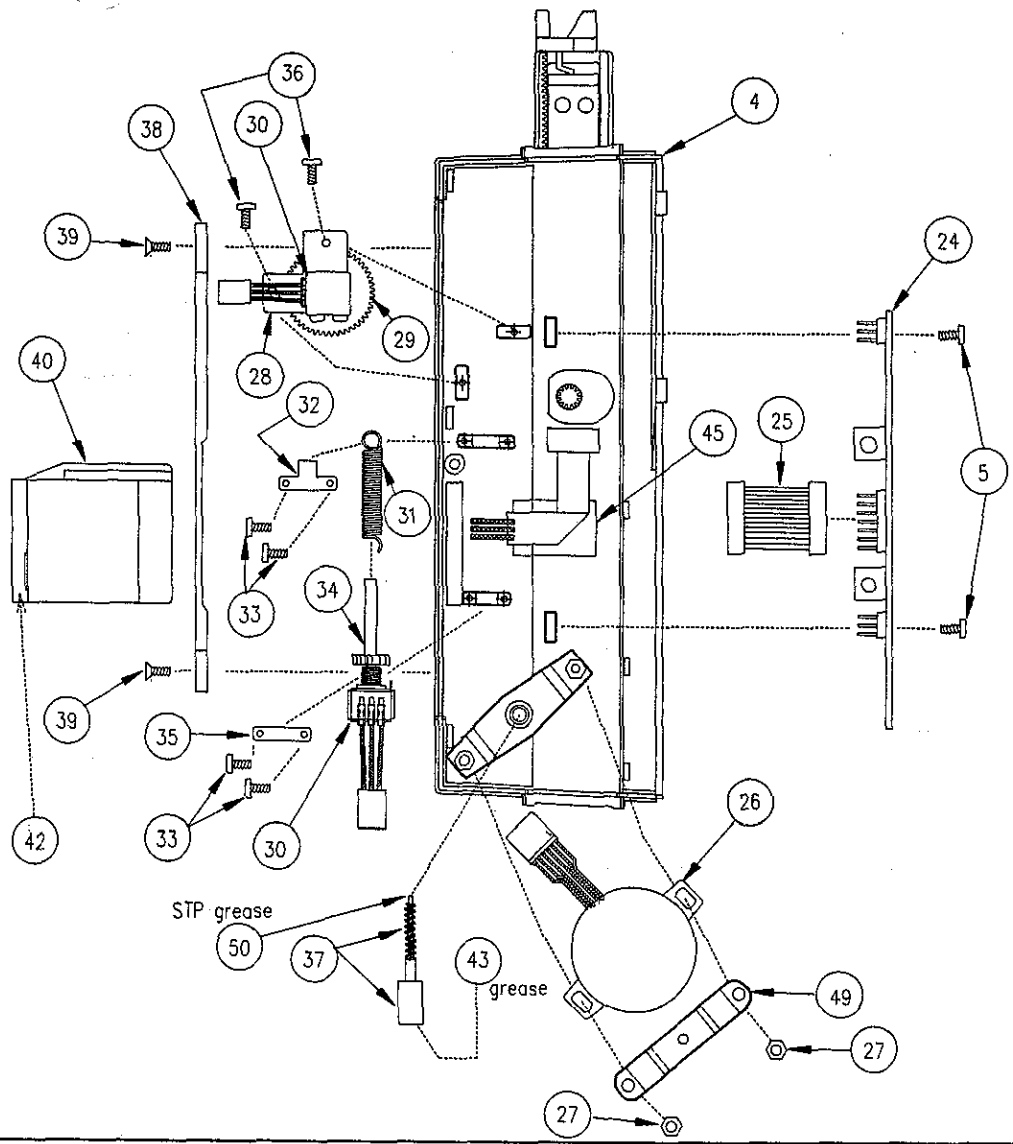


ATTENTION
OBSERVE PRECAUTIONS FOR HANDLING ELECTROSTATIC SENSITIVE DEVICES
S420 Printed by LABELMASTER, CHICAGO, IL 60646

NOTE: REF 3-68-20A02-0-X FOR ASS'Y PROCEDURE

medexinc

Slide Housing S/A
Part No. 1-68-20A02-0-6
Sheet one of two



medexinc

Slide Housing S/A
Part No. 1-68-20A02-0-6
Sheet two of two

ASSEMBLY INSTRUCTIONS (3-68-20A02-0-X)

**Safety Glasses Required*

NOTES: *(1) All 2-56 screws are to be torqued 10 inch/ounces).*
(2) All 4-40 screws are to be torqued 16 inch/ounces.

1. Cut a length of double coated tape (45) the size of the long side of the syringe chimney on the slide top housing (4). Cut the piece of tape in half length wise. Remove one side of the backing and place the tape on both long sides of the chimney. Remove the backing from the other side of the double coated tape and install the clamp seal (21).

2. Cut a length of double coated tape (45) approximately 1 inch long. Place the tape on the slide housing subassembly (4) centered 3/4 inch from the inside edge of the cable seal. (Tape is used to secure pressure transducer cable, see step 21).

3. Press the cluster gear (8) through the slide housing subassembly (4). Secure the cluster gear with an E-clip (1). Apply pressure to the small gear side of the cluster gear to seat the E-clip.

4. Paint the bottom edge of syringe clamp (40) with black paint (42) if necessary. Insert the syringe clamp (40) through the clamp seal (21, already installed) into the syringe chimney. Turn the unit over with the syringe rack facing up.

5. Select one of the two potentiometer subassemblies (30). Bend the locating tab from it's 90 degree position to 180 degrees. The tab is not used in this application. The locating tab should be on the same plane as the top surface of the potentiometer.

6. Install the clamp gear (34) to the potentiometer with the bent locating tab.

7. Find the slide torsion spring (31). Install the slide torsion spring onto the clamp gear with the clipped end of the spring toward the gear. Insert the clipped end into the slots in the gear. Examine the other side of the gear. The clipped end of the spring should not extend beyond the end of the gear. If the clipped end of the spring extends beyond the end of the gear the spring must be nipped closer (safety glasses should be worn) until the end of the spring does not extend beyond the gear.

8. Pick up the above mentioned potentiometer, gear, and spring and orient the potentiometer toward the end of the slide subassembly (4) with the motor mount. Using your fingers, rotate the gear toward yourself until it stops. Place the above-mentioned potentiometer, gear and spring into both of the half round mounting recessed on the slide subassembly (4). Slide two pan head screws (33) into the potentiometer clamp (35). The heads of the screws should be on the opposite side of the half moon shaped cutout on the clamp. Place the potentiometer clamp (with

the syringe plunger holder (on the track). Insert the clutch assembly into the side of the slide housing and into the square of the track assembly. Slide the clutch assembly toward the side of the square with tabs. (There is a slot in the track for the tabs). Insure that the pressure transducer cable is clear of the clutch assembly. Insert the clutch key in the space left in square hole. Apply pressure to insure that the clutch key is fully seated.

16. Insert the clutch actuator (7) into the clutch assembly from the top of the track. Attach the clutch lever (3) and slide the clutch actuator up into the clutch lever. Attached the clutch cover with the two screws (5) (screws are 4-40).

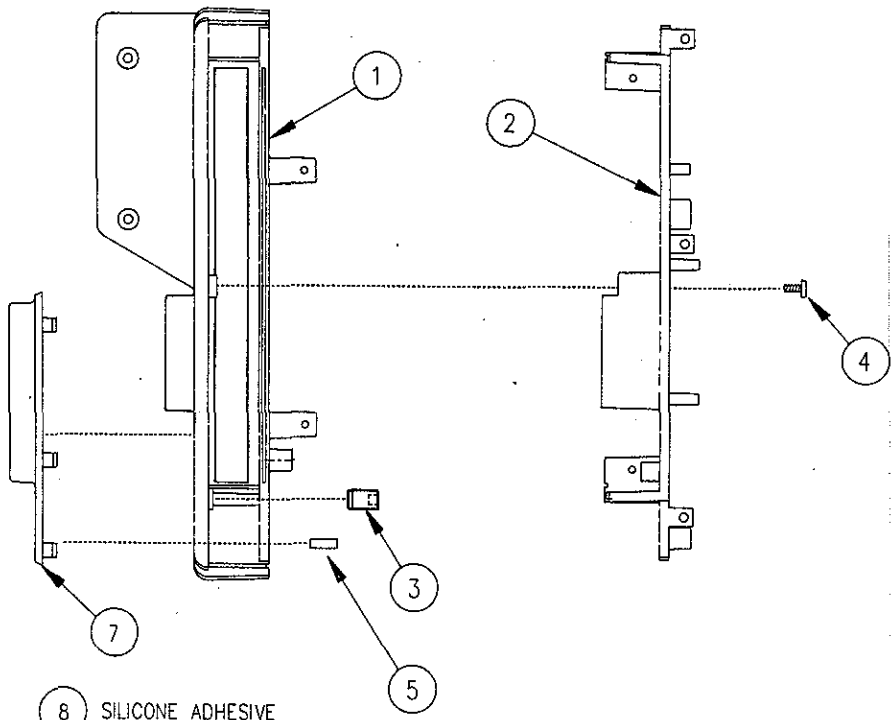
17. Attach the position potentiometer holder (28) to a potentiometer subassembly (30) with the hardware supplied. Be sure the locating lug on the potentiometer is in the slot provided on the holder. Push the position gear (29) onto the pot. Rotate the gear to the full counter clockwise position. Make sure the track is locked by the syringe clamp in the empty position. Install the potentiometer subassembly into the mounts provided and engage the potentiometer gear with the cluster gear. Reset the teeth on the potentiometer position gear 5 teeth counter clockwise. Reengage the potentiometer assembly with the cluster gear. Install the two pan head screws (36). Adjust the gap between the two gears to a minimum. Tighten the screws lightly. Move the track from end to end to check for excessive tightness and backlash. Readjust the potentiometer if necessary.

18. Apply STP grease (50) to the round end of the leadscrew (10). Place the thrust bearing (11) over the greased end of the lead screw. Open the clutch (use the clutch lever) and with the greased end of the lead screw going into the end of the slide housing with the large hole pass the lead screw through the clutch. Release the clutch and align the thrust bearing hole in the top of the slide. Press the thrust bearing until seated into the top of the slide assembly. Find two E-clips (14) and making sure the flat side (or dull side) is up (or shiny side down), attach the two E-clips with pliers to the top of the leadscrew.

19. Turn the slide housing up with the square end of the leadscrew facing toward the ceiling. Slide on the water seal with the cupped end facing the leadscrew. Slide on the lead screw bearing (9). With the bearing insertion tool (0-47-20002-0-X), press firmly into the slide bottom. Turn the slide around and press firmly the end of the leadscrew where the two E-clips are. Make sure there is play (end clearance) and that the leadscrew can rotate freely. If the leadscrew moves freely, slide worm gear (20) onto the end of the leadscrew. Secure the worm gear with an E-clip. Make sure the flat (or dull side) of the E-clip is facing out (or shiny side down). Check the manual operation of the track and slide. Depress the clutch lever and move the track from end to end. The track should move freely and not bind excessively in the slide. The clutch should clear the leadscrew. There should not be excessive "grinding" of the clutch against the leadscrew.

20. Snap the slide door (38) into the slide housing and secure with two Phillips screws (39).

REV	REF	DESCRIPTION OF REVISION	VED	DATE
A	91060302	SAFETY WARNING ADDED	D. AMMANN	6-14-91
			R.BOOTH	6-14-91
2	91101402	NEW SADDLE AND ADD SADDLE PINS, REMOVED SOLVENT BONDING OF SADDLE.	D. AMMANN	10/18/91
			R.BOOTH	10/22/91
2A	93032206	ASSEMBLY INST. MOVED TO 3-68-20A03-0-X		5/26/93
				6-1-93



ASSEMBLY INSTRUCTIONS:

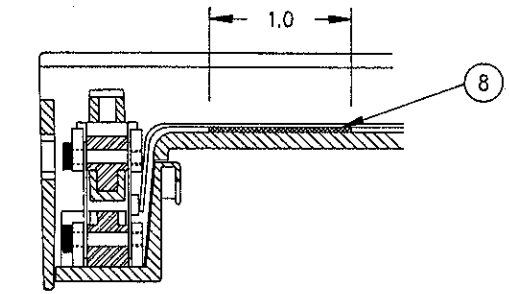
SAFETY GLASS REQUIRED: REFER TO 3-68-20A03-0-X FOR ASSEMBLY INSTRUCTIONS

medexinc

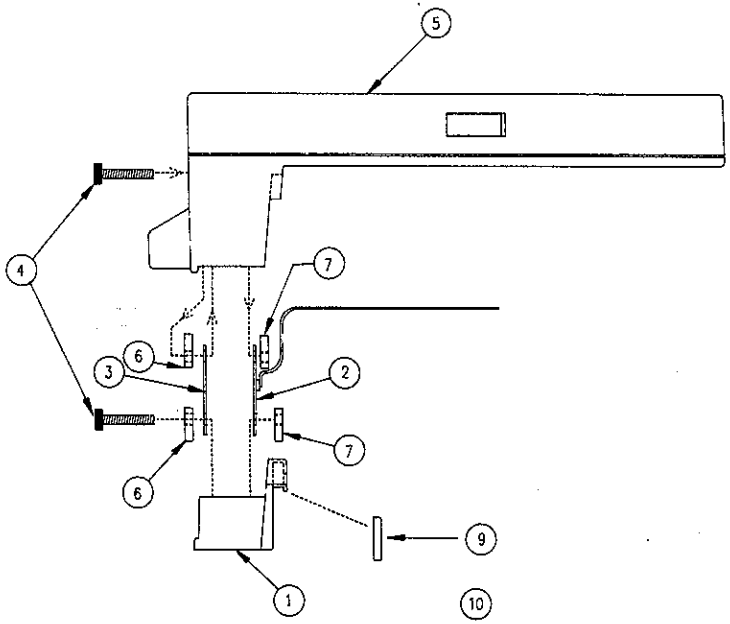
Slide S/A

Part No. 1-68-20A03-0-2

REV	DCN #	DESCRIPTION OF REVISION	APPROVL	DATE
1	90103101	ITEMS 9 & 10 WERE ADDED	R. BOOTH	11-01-90
			D.AMMANN	11-01-90
A	91060302	SAFETY WARNING ADDED	D.AMMANN	6-14-91
			R. BOOTH	6-14-91
B	92100701	REVISED PROCEDURE	[illegible]	11/20/92
			[illegible]	11-20-92



ASSEMBLED CROSS SECTION



ASSEMBLY INSTRUCTIONS:

* SAFETY GLASSES REQUIRED

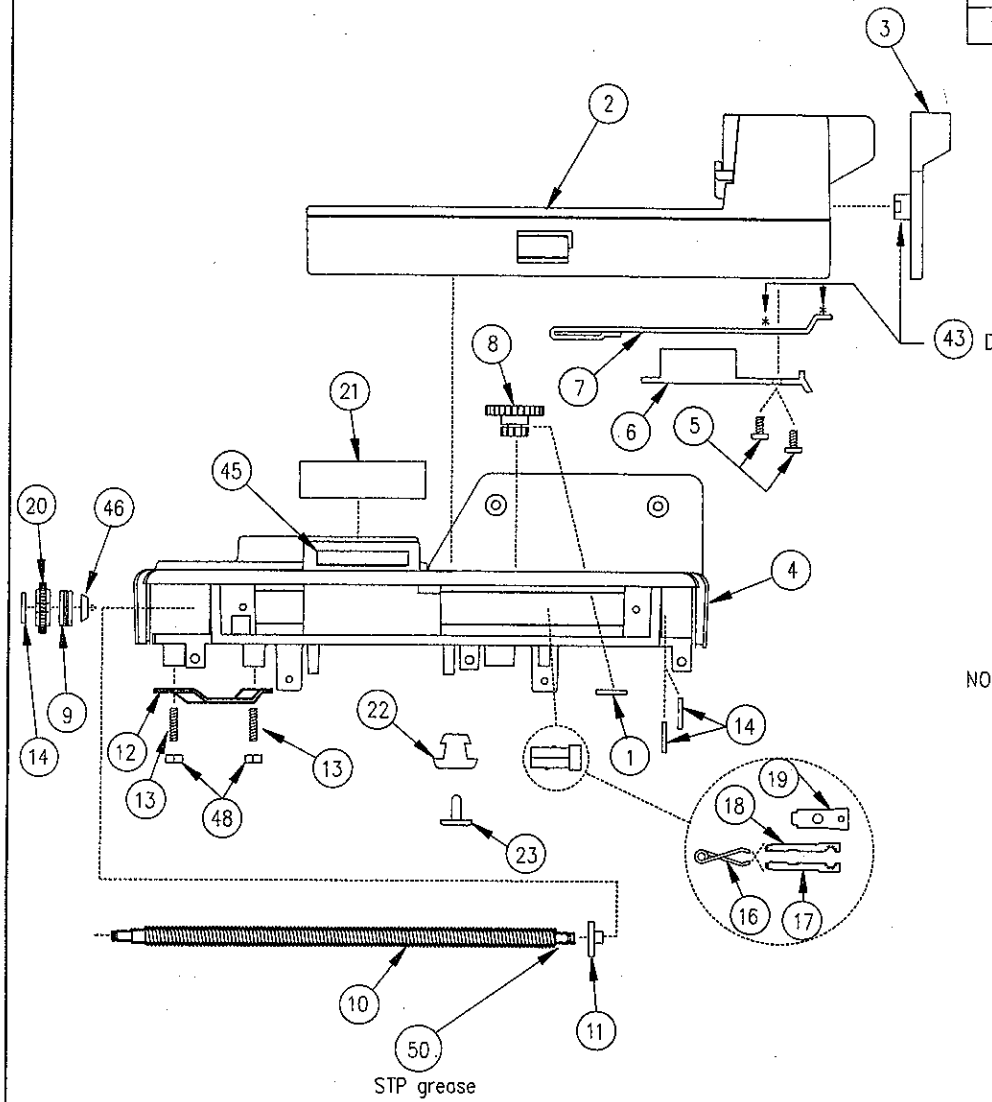
1. INSERT TRANSDUCER NUT PLATE (7) (NOTE ORIENTATION) INTO PLUNGER HOLDER (1).
2. INSERT FORCE SENSOR PLATE WITH CABLE (2) BETWEEN TRANSDUCER NUT PLATE (7) (NOTE CABLE ORIENTATION) AND PLUNGER HOLDER (1).
3. INSERT BLANK SENSOR PLATE (3) AND SCREW PLATE (6) (NOTE ORIENTATION) INTO PLUNGER HOLDER (1). ALIGN (2) & (3) BEFORE TIGHTENING SOCKET HEAD SCREW (4). TORQUE TO A SCREWDRIVER SETTING OF 20 IN/LB.
4. PLACE PLUNGER HOLDER ASSEMBLY INTO TRACK.
5. INSERT TRANSDUCER NUT PLATE (7) (NOTE ORIENTATION) INTO ASSEMBLY. DO NOT PRESS INTO THE RIBBON CABLE. HOLDING THE NUT PLATE WITH ONE HAND, TILT THE ASSEMBLY UPRIGHT AND PLACE THE TRANSDUCER SCREW PLATE (6) (NOTE ORIENTATION) INTO POSITION. ENSURE ALIGNMENT OF ALL PARTS. SECURE REMAINING SOCKET HEAD SCREW (4) INTO POSITION.
6. INSERT SHIMS TO CENTER PLUNGER HOLDER. TIGHTEN REMAINING SOCKET HEAD SCREW TO 20 IN/LBS.
7. PLACE ABOUT ONE INCH OF DOUBLE SIDED TAPE (8) ON INSIDE OF TRACK (5).
8. PRESS ON CABLE TO SECURE TO TAPE.
9. GLUE PLUNGER RETAINER (9) TO PLUNGER HOLDER (1) WITH GLUE (10). SIGN & DATE "ASSEMBLED BY" LINE.
10. A) INSERT FLEX CABLE PINS INTO 3 POSITION CONNECTOR ON AUX PCB OF TRACK TEST PUMP.
    B) ADJUST TRIMPOT (VR2) FOR HEX # $\geq$ 10
    C) USING FORCE CALIBRATOR, ADJUST FORCE TO 16#, ENSURE HEX# $\geq$ 80
    D) REPEAT FOR EACH PLGR/TRACK S/A OF THE APPLICABLE W/O.
    E) SIGN & DATE "TESTED BY" LINE
11. WHEN READY FOR RELEASE TO QC, SIGN & DATE "RELEASED BY MFG" LINE.

medexinc®

Plunger Holder Track S/A

Part No. 1-68-20A04-0-1

REV	DCN#	DESCRIPTION OF REVISION	APPROVED	DATE
1	94011904	ADD GREASE	B. Stillwell O. Parker	1-20-94 1-20-94



NOTE: REF 3-68-20A02-0-X FOR ASS'Y PROCEDURE

medexinc

Slide Housing-2 S/A
Part No. 1-68-20A07-0-1